The estimated annual industry costs (not discounted) are summarized in Table 2. These annual costs vary over the first four years as the new HACCP-based program is undergoing its implementation phase. After the initial four years, the recurring costs are estimated at a constant $99.6 to $119.8 million per year. The present value of all industry costs summarized in Table 2 for the 20-year time period is $968 to $1,156 million as shown earlier in Table 1. This total of $968 to $1,156 million ($0.97 to $1.16 billion) is the total industry cost for the rule as shown in Table 3.

TABLE 2.—SUMMARY OF ANNUAL INDUSTRY COSTS—ALL REQUIREMENTS

[$ Thousands]

Cost Category	Year 1	Year 2	Year 3	Year 4	Year 5+
I. Sanitation SOP's:					
Plans and Training	2,992				
Observation and Recording	8,345	16,691	16,691	16,691	16,691
II. *E. coli* Sampling:					
Plans and Training	2,627				
Collection and Analysis	8,716	16,122	16,122	16,122	16,122
Record Review	406	752	752	752	752
III. Compliance with *Salmonella* Standards		5,472–16,899	5,353–25,753	5,811–25,956	5,811–26,079
Compliance with Generic *E. coli* Criteria		(1)	(1)	(1)	(1)
IV. HACCP:					
Plan Development		3,769	27,755	35,464	
Annual Plan Reassessment			69	448	1,179
Initial Training		1,270	8,284	18,435	
Recurring Training		64	542	1,877	2,799
Recordkeeping (Recording, Reviewing and Storing Data)		3,050	18,479	42,478	54,097
V. Additional Overtime		189	837	1,711	2,125
Total	23,086	47,379–58,806	94,884–115,284	139,789–159,934	99,576–119,844

[1] Not Separately Estimated.

TABLE 3.— PRESENT VALUE OF 20-YEAR COSTS AND BENEFITS

[$ Billions]

Effectiveness in reducing pathogens in the manufacturing sector (percent)	Public health benefits		Industry costs
	Low	High	
10	0.71	2.66	0.97–1.16
20	1.43	5.32	0.97–1.16
30	2.14	7.98	0.97–1.16
40	2.85	10.64	0.97–1.16
50	3.57	13.30	0.97–1.16
60	4.28	15.96	0.97–1.16
70	4.99	18.61	0.97–1.16
80	5.71	21.27	0.97–1.16
90	6.42	23.93	0.97–1.16
100	7.13	26.59	0.97–1.16

Note: Analysis assumes zero benefits until year 5. All elements of the HACCP-based program will be in place 42 months after publication of the final rule.

The public health benefits of this rule are discussed in detail in Section IV. The benefits are based on reducing the risk of foodborne illness due to *Campylobacter jejuni/coli, Escherichia coli* 0157:H7, *Listeria monocytogenes* and *Salmonella*. Section IV concludes that these four pathogens are the cause of 1.4 to 4.2 million cases of foodborne illness per year. FSIS has estimated that 90 percent of these cases are caused by contamination occurring at the manufacturing stage that can be addressed by improved process control. This addressable foodborne illness costs society from $0.99 to $3.69 billion, annually. The high and low range occurs because of the current uncertainty in the estimates of the number of cases of foodborne illness and death attributable to the four pathogens. Being without the knowledge to predict the effectiveness of the requirements in the rule to reduce foodborne illness, the Department has calculated projected health benefits for a range of effectiveness levels, where effectiveness refers to the percentage of pathogens eliminated at the manufacturing stage. The link between effectiveness and health benefits is the proportionate reduction assumption which is explained in Section IV. Because of the wide range in estimates for the cost of foodborne illness, each effectiveness level will have a low and high estimate for public health benefits. These estimates of public health benefits are shown in Table 2, as the present value of a 20-year benefit stream.

The analysis assumes that benefits will begin to accrue in year five. The five year lag leads to conservative benefit estimates since the new HACCP-based inspection program will be fully implemented in 42 months, and benefits should accrue during those 42 months as well as in the 1½ years that follow. Limiting the benefit estimates to four pathogens also leads to conservative cost estimates. To the extent that the proportionate reduction estimate may overestimate benefits, these other factors provide conservative balance.

Net benefits exist for every cost and benefit combination illustrated in Table 2 except for the case of 10 percent effectiveness using the low benefit estimate. If the low benefit estimate is correct, the new HACCP-based regulatory program would have to reduce pathogens by 14 to 17 percent to cover the projected 20-year industry costs of $968 to $1,156 million. For the high benefit estimate net benefits begin to occur at an effectiveness level of 4 to 5 percent.

The costs summarized in Tables 1 and 2 have not been reduced to account for firms that already have existing HACCP programs. FSIS does not have a good estimate of the number of such firms.

C. Impact on ''Smaller'' Businesses

The final rule provides regulatory flexibility for smaller firms consistent with the Regulatory Flexibility Act. For the slaughter facilities, the generic *E. coli* sampling requirements vary depending on the number of birds or animals slaughtered annually. This will significantly reduce the microbial

testing costs for smaller establishments which, under the proposed rule, would have been required to test every species or kind they slaughter every day on which slaughter of that species or kind occurs. Under the final rule, the impact on smaller establishments is mitigated by the change to base generic *E. coli* sampling requirements on annual production and by a change to no longer require that every species or kind be sampled. The costs to small establishments are also reduced because the proposed carcass cooling and antimicrobial near term requirements have been eliminated from the final rule and training requirements are more flexible. The requirement to sample each variety of raw ground product, which caused a heavier burden on small establishments, has also been eliminated.

The regulatory burden on small establishments is eased by the provisions which extend the time small establishments have to meet the HACCP system requirements. The detailed cost analysis in Section V outlines the methodology used in developing cost estimates and varying regulatory requirements for the purpose of regulatory flexibility for small establishments.

D. Effect on Retail Price

The preliminary analysis included an estimate that the total four-year implementation costs represented only $0.0024 per pound of fresh meat and poultry. This type of estimate helps put overall cost figures into perspective in terms of the potential increase in food prices. A large number of smaller processors responded very emotionally to the low figure of $0.0024 per pound on the basis that the lack of economies of scale in their businesses means their potential unit cost increases would be far higher. This ''cost-per-pound'' analysis was not meant to imply that the cost impact on all business would be the same. In a competitive industry, the impact on overall retail price is, however, an important indicator of net societal benefits. The four-year implementation costs for the final rule represent $0.0011 to $0.0013 per pound based on 1993 production of 67.15 billion pounds (66.4 billion pounds federally inspected and 748 million state inspected) of meat and poultry on a carcass weight basis. The annual recurring cost of $99.6 to $119.8 million represents $0.0015 to $0.0018 per pound based on 1993 production.

E. Impact on International Trade

The final rule will have an impact on countries and the establishments in those countries that export meat and poultry products to the United States. The inspection statutes require that imported product be produced under an inspection system that is equivalent to the U.S. inspection system. The equivalence of a country's system must be established by the United States before product can be exported to the United States. The notion of equivalence has been clarified under the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary measures. Under the WTO, all members have an obligation to apply the principle of equivalence on importing countries. Equivalence determinations are based on scientific evidence and risk assessment methodologies.

In light of the WTO emphasis on the use of science to determine equivalence, a number of countries are moving toward implementation of HACCP systems. The preliminary analysis noted that a large portion of the eligible exporting establishments are in countries that are themselves in the process of implementing HACCP and complying with their own country's HACCP requirements may achieve equivalence with the requirements of this rule.

As of January 1, 1995 there were 1,395 establishments in 36 different countries certified to export meat or poultry products to the United States. Canada (599 establishments), Denmark (125 establishments), Australia (111 establishments) and New Zealand (94 establishments) accounted for two-thirds of the 1,395 establishments. These four countries were the source of 85 percent of the 2.6 billion pounds of product imported during 1994. These four countries are currently developing HACCP systems for their respective inspection programs.

Half (18) of the 36 countries have fewer than 10 establishments approved to export products to the U.S. These 18 countries represent a total of 77 establishments, 5 percent of the total. Meeting the equivalency requirements may present a problem for some of these countries in the near term. Their inspection programs will have to meet equivalency requirements for HACCP according to the implementation schedule for domestic establishments, i.e., 18 months for large establishments, 30 months for small establishments and 42 months for very small establishments. This schedule should lessen the burden on smaller establishments.

There are other factors that will affect the burden on foreign establishments. As HACCP becomes the international norm, these establishments will be required to implement changes to meet the requirements of other countries implementing HACCP. Thus, their costs may not be solely associated with U.S. requirements. Establishing impact is further complicated because the U.S. requirements apply only when they are preparing product that is to be exported to the U.S. This product may represent only a small portion of total establishment production.

Upon implementation of these regulations, FSIS will review other countries' meat and poultry systems to ensure that exporting countries have adopted comparable measures, which would entitle them to continue exporting product to the United States. As other countries improve their regulations by adopting provisions comparable to those contained in this rule, it is expected that U.S. exports will similarly be affected, i.e., the receiving countries will be closely reviewing domestic exporting establishments to assure that they are meeting the requirements of the importing country.

FSIS will continue to carry out its import inspection responsibilities with a two-stage approach. The first stage is system review, which consists of an evaluation of the laws, policies, and administration of the inspection system in each eligible country. This overall evaluation will include an assessment of the implementation of HACCP supplemented by on-site reviews of individual establishments, laboratories, and other facilities within the foreign system. The ''equivalency'' of foreign requirements will be determined at this stage.

The second level of review involves port-of-entry inspection by FSIS inspectors to verify the effectiveness of foreign inspection systems. Using statistical sampling plans based on the foreign establishment's history and the nature of the product, FSIS will continue to give greater scrutiny to shipments posing the highest risk. Products that do not meet U.S. requirements, which includes having been produced under a HACCP or HACCP-equivalent system, will be refused entry. FSIS has concluded that requiring HACCP systems in combination with the two-stage inspection approach will better ensure the safety of imported meat and poultry products.

All countries exporting raw products to the U.S. must develop and implement performance standards that are equivalent to the pathogen reduction performance standards for *Salmonella.* They must also be able to demonstrate that they have systems in place to assure

compliance with the standards. As with any other type of standard, FSIS could choose to test imported product for *Salmonella* at port-of-entry to verify the effectiveness of the foreign inspection system.

With respect to the specific requirements for sampling generic *E. coli* to validate control of slaughter and sanitary dressing procedures, it will be necessary for all foreign countries to demonstrate that they have an equivalent procedure to verify that they are controlling their slaughter and sanitary dressing processes.

There were several comments related to trade issues. Most of the comments concerning the impact on exports dealt with the proposed requirement for antimicrobial treatment of U.S. product. That proposed requirement raised particular concerns because the European Union member states and Canada restrict the use of certain antimicrobials on meat and poultry carcasses. The concerns raised in the comments are no longer an issue because the final rule does not require the use of antimicrobials. The final rule will affect exports only if a company has difficulty meeting the microbial performance criteria without using an antimicrobial. One option discussed in the proposed rule was that hot water would be considered to be an acceptable antimicrobial treatment, and that would be acceptable to Canada and the members of the European Union. The public comments also indicated that Trisodium Phosphate (TSP) is approved for use in Canada and the United Kingdom and is being considered by the European Union, Australia, and New Zealand.

Comments related to imports were concerned about the procedures FSIS would use to determine equivalence with the new U.S. requirements. As a condition of the NAFTA Treaty and the GATT Treaty, the United States has agreed to allow imports from countries that have systems of inspection equivalent to that of the United States. FSIS is considering alternative methods for determining that a foreign country's system of inspection can assure that the establishments within that system are using a process control system equivalent to the HACCP-based inspection system outlined in the final rule.

F. Impact on Agency Costs

Implementation of this rule will lead to both one-time nonrecurring costs and recurring costs for FSIS. There are three categories of one-time nonrecurring costs: (1) Training, (2) in-establishment demonstration projects, and (3) laboratory renovation. In order to implement the rule, FSIS will provide training to in-establishment personnel in two segments. The first training segment will cover issues related to sanitation standard operating procedures and generic *E. coli* sampling and testing requirements. The estimated costs for this activity is $3.6 million in the first year of implementation. The second training segment will cover issues related to the implementation of HACCP and is estimated the cost $3.6 million spread over the second and third year of implementation. FSIS will utilize the train-the-trainer approach to minimize the costs of these initiatives. FSIS is also committed to working with States and industry to sponsor HACCP demonstration projects for small businesses. Pursuant to implementation of the HACCP rule, microbiological sampling and testing will increase dramatically. In the period from 1990 to 1995, FSIS averaged approximately 33,000 analyses for microbiology per year. This is estimated to increase to 125,000 analyses per year after HACCP implementation. In order to accommodate this increase, FSIS will renovate its field laboratory facilities to expand their capacity, improve ability to test for a broader range of pathogens, and purchase new equipment. FSIS estimates that the planned renovation will cost $1.5 million.

By implementing this rule, FSIS will incur recurring costs associated with increased microbiological testing and upgraded inspector salaries. FSIS estimates that microtesting costs will increase approximately $3.0 million annually. Of this amount $2.0 million is needed for equipment, supplies, and shipping costs to conduct *Salmonella* testing, $0.5 million for microtesting conducted to verify HACCP systems, and $0.5 million for personnel necessary to handle the increased workload. Under HACCP-based inspection, FSIS personnel will be required to assume greater responsbility for more complex food inspection tasks. Slaughter inspectors will be required to perform health and safety tasks, such as taking microbiological samples, and verifying HACCP systems. Processing inspectors' roles will take them out of the establishment and put them into retail and market place settings to take microbiological samples, and to ensure meat and poultry products are handled in a manner to that minimizes the growth of pathogenic organisms. FSIS estimates that compensating inspectors for assuming more complex food safety tasks will cost $1.6 million per year.

G. Impact on State Programs

Comments stated that FSIS failed to adequately consider the cost of the changes to State programs and that FSIS was increasing the resource demands for State programs without providing adequate funding. The preliminary analysis did not address the impact on State programs. However, FSIS recognizes that the 26 States operating their own meat and poultry inspection programs will likely have to substantially modify their programs after the HACCP/Pathogen Reduction regulation is finalized to remain ''at least equal to'' Federal inspection programs as required by the FMIA and PPIA. During the regulation's implementation period, FSIS will be using the Agency's State-Federal Program staff to assist the States in bringing the necessary changes to the State inspection programs. Although FSIS has requested some additional funds to implement this rule, FSIS has also acknowledged that implementation of this rule will require eliminating some tasks, conducting other tasks differently and streamlining the organization in order to free up resources to fully address the new requirements. FSIS believes that the same type of restructuring or reprogramming will take place within the State programs. This does guarantee, however, that all States with inspection programs will be able to implement the necessary program changes without additional funds. FSIS believes, however, that with FSIS assistance and with the flexibility provided under the ''equal to'' provisions, most of the States should be able to modify their programs with minimal additional funding. To the extent that there are any additional costs, the State inspection programs are eligible to receive up to 50 percent Federal matching funds.

H. Consumer Welfare Analysis

It is likely that at least some of the costs of the new HACCP-based regulatory program will be passed on to consumers in the form of higher prices. Even if costs are fully reflected in retail prices, the impact on consumers and consumption will be small. Retail costs are not expected to increase more than 0.02 percent. Retail demand for meat and poultry is inelastic. A likely range is -0.25 to -0.75. This suggests changes in quantity demanded of less than 0.02 percent. Given that annual per capita meat and poultry consumption is about 211 pounds, retail weight, the impact on individual consumption will be less than 1/10th of a pound per year. In aggregate, with a high impact

scenario, consumption would decrease by about 50 million pounds. These impacts may be overstated if meat and poultry producers pass some costs back to livestock and poultry producers. Improved consumer confidence in the safety of meat and poultry could offset price driven decreases in consumption.

IV. Analysis of Public Health Benefits

A. Introduction

This section addresses the methodology used to develop the estimates for public health benefits that, for the purpose of this final Regulatory Impact Assessment, have been defined as the reduction in the cost of foodborne illness attributable to pathogens that contaminate meat and poultry products at the manufacturing stage. This section is organized around the Agency's responses to the public comments related to benefits. The first part of this section addresses the general comments related to risk assessment. The Agency has responded to these general requirements by providing an overall summary of the current state-of-the-art with respect to risk assessment for foodborne pathogens. The second part of the discussion (see subsection titled ''Analysis of Comments on Public Health Benefits'') addresses the more specific comments on the methodology used to estimate benefits in the preliminary analysis.

Several comments suggested that FSIS has not conducted an adequate risk assessment and/or should conduct a thorough risk assessment before proceeding with the current rulemaking. More focused comments assert that the relationship between pathogen reduction at the manufacturing stage and foodborne illness reduction is unknown. Those comments suggest that establishing that relationship requires a quantitative risk assessment, i.e., an estimate of the probability of adverse health effects (foodborne illness) given a particular level of a hazard (pathogens at manufacturing stage).

The preliminary analysis and this final RIA recognize that the relationship is unknown and acknowledge that there are significant data gaps regarding both likelihood and magnitude of illness and numbers of foodborne pathogens. These data gaps mean that multiple assumptions must be made in order to calculate the probabilities of risk, and FSIS is concerned with this tremendous uncertainty. However, the agency is developing quantitative assessments and believes that these will become the basis on which to make future regulatory decisions. In this rulemaking, FSIS estimates of the risk of foodborne disease linked to specific pathogens are based upon the best judgement of nationally recognized experts in infectious disease, epidemiology, microbiology, and veterinary medicine. FSIS is also relying on a qualitative estimation of risk as expressed in publications and summary reports from the CDC, other public health agencies, and special panels, such as the National Advisory Committee on Microbiological Criteria in Foods and those established by the NAS. Based on this sizable body of information and scientific judgement, FSIS is proceeding to develop benefit estimates using the assumption that a reduction in pathogens leads to a proportionate reduction in illness and death. The benefits analysis could have used a more conservative relationship estimate, e.g., a reduction in pathogens leads to a reduction in illness that is less than proportional. However, given the current level of knowledge, FSIS views the proportional assumption as most appropriate at present.

The Department has initiatives in place that will begin to relate pathogen levels at inspected establishments to incidence of human illness and support quantitative risk assessment (see Section IV–D on FSIS Data Initiatives). The present paucity of data to support a risk model for the major foodborne pathogens causing human disease limits the usefulness of quantitative risk assessment in the regulatory arena of meat and poultry inspection. It is unlikely that any single numerical constant will adequately describe the dose-response relationships for all pathogens associated with all of the products that FSIS regulates, given the complexity of possible interactions of factors associated with the host, the pathogenic strain, the diet, and the environment (CAST, 1994).

The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103–354) now requires that for each proposed major regulation (i.e. economic effects of at least $100 million a year and effects on human health, safety, or the environment) the Department publish an analysis of the risks addressed by the regulation. While this statute does not apply to this final rule, FSIS is providing a qualitative estimation of risk (Tables 4 and 5) and a recommendation to manage risk using HACCP in meat and poultry inspection programs. Concurrently, scientists from FSIS and USDA's Agricultural Research Service (ARS), Economic Research Service (ERS), and modelers from academia and industry continue to develop risk models which blend failure analysis, predictive microbiology, and other models into the framework described by the NAS (NRC, 1983). FSIS believes this approach is flexible and responsive to new data necessary to fully document risks of foodborne diseases.

B. FSIS Risk Assessment

Following the publication of the 1985 National Academy of Sciences (NAS) study on the scientific basis for meat and poultry inspection, FSIS requested that the National Research Council of NAS conduct a follow-up study that included the objective of developing a risk assessment model for the poultry production system. The subsequent report, ''Poultry Inspection: The Basis for a Risk-Assessment Approach'' was published by the National Academy Press in 1987. The 1987 study concluded that the present system of inspection provides little opportunity to detect or control the most significant health risks presented by microbial agents that are pathogenic to humans. The study also concluded that current databases can serve as the basis for a comprehensive, quantitative risk assessment only for certain well-characterized chemical residues.

The committee conducting the study also concluded that their report did constitute a qualitative risk assessment that could be useful for many purposes, including the evaluation of inspection strategies. That assessment found: ''There is evidence linking disease in humans to the presence of pathogens on chickens. For example, epidemiological studies indicate that approximately 48% of *Campylobacter* infections are attributable to chicken. Data also suggest that chicken is probably an important source of salmonellosis in the United States.'' Based on these and other findings, the committee recommended that FSIS ''modify the existing system so that it more directly addresses public health concerns.'' FSIS believes that the implementation of HACCP programs at slaughter for meat and poultry is such a ''modification'' of the food safety system which will address human health hazards, particularly foodborne diseases.

C. Risk Assessment Framework

The National Research Council (1983) presented a framework for risk assessment that has become a standard paradigm to organize risk assessments for chemical and microbial hazards. The framework, consisting of hazard identification, dose-response assessment, exposure assessment, and risk characterization, is flexible and can accommodate many different modeling strategies. The major distinction

between foodborne microbial risk assessments and chemical risk assessments may be the additional uncertainties of microbial growth and survival in food prior to consumption. Survival of pathogens present in a raw food and after cooking can be modeled using predictive microbiology methods. These models can also address the growth of pathogens with time and temperature abuse of raw and cooked foods.

One of the first U.S. publications on the application of predictive microbiology to microbial risk assessment (Buchanan & Whiting, 1996) included estimations of risk of salmonellosis for several ''what-if scenarios'' as examples of potential time and temperature abuses of partially cooked food. The predictive microbiology model was linked to a published dose-response model for salmonellosis (Haas, 1983) to calculate a risk estimate. The dose-response model was developed by empirically fitting data from human feeding studies conducted at high-dose challenges with a number of pathogenic strains of *Salmonella* to the ''beta poisson'' model (Haas, 1983). The authors generated risk estimates for selected cooking and abuse scenarios, but recognized that the risk of illness is zero when the pathogen is not present in the sample even with unsafe food handling. HACCP programs at slaughter are expected to affect pathogen presence and levels before potential time and temperature abuses can occur. Therefore, changes at slaughter, in the duration of cooking, and final storage conditions of the food exert a tremendous impact upon the model outcomes.

An unpublished draft risk model is in development as a research endeavor by Agriculture and Agri-Food Canada and Health Canada. A variety of modeling approaches were organized within the 1983 NRC framework to estimate risk of human illness from *E. coli* 0157:H7 in ground beef. The draft risk model includes many stochastic variables to account for the variability and uncertainty associated with the inputs and assumptions of the model. The authors are developing the model to identify current limitations to the construction of quantitative models which accurately describe the risk of foodborne disease along the farm to fork continuum.

These recent quantitative risk assessment efforts are an encouraging beginning and serve to illustrate the tremendous uncertainties created by insufficient data describing processes throughout the farm to table continuum that contribute to risk. Additional uncertainties surround assumptions based on epidemiologic data for human illness. For example, recent data in the U.S. indicates a growing number of outbreaks of *E. coli* 0157:H7 disease linked to sources other than ground beef. The ecology of the organism on the farm, in the bovine gastrointestinal tract, and in irrigation, recreational, and drinking waters is largely unknown. Additionally, the primary sources of *E. coli* 0157:H7 causing sporadic disease may remain undercooked hamburger and may differ from vehicles causing outbreaks, as has been documented for *Campylobacter* (CDC, 1988). Outbreaks of campylobacteriosis have been caused primarily by unpasteurized milk and contaminated water, yet the overwhelming majority of infections are sporadic and have been linked to undercooked chicken. Control strategies to reduce both outbreak and sporadic case numbers for both of these pathogens may require greater understanding of vehicles of disease and more information than is currently available.

FSIS concludes that risk models for foodborne illnesses are necessarily based largely on assumptions because scientific data describing key foodborne disease processes have not been developed. The models are extremely useful to identify basic research needs that might reduce the uncertainty associated with the inputs and assumptions of the models. The agency is proposing initiatives to generate data which may reduce uncertainties associated with modeling the risk of foodborne diseases. However, application of microbial risk assessment models to regulatory decision-making appears premature at this time. The following is a summary of the availability and limitations of data supporting risk assessment for foodborne pathogens:

1. Hazard Identification

The Agency selected from the pathogens listed in Tables 4 and 5 the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* 0157:H7, *Salmonella* and one environmental pathogen *Listeria* monocytogenes for consideration in risk assessment. FSIS believes that these four pathogens may contaminate meat and poultry food vehicles at slaughter and can be reduced through improved process control in the manufacturing sector. Available data on estimated human disease incidence are summarized in Table 4. Data on human disease attributable to proven as well as epidemiologically linked pathogens and food vehicles are presented in Table 5. Additional and more precise information for this section regarding estimated national disease incidence and disease severity and duration is expected on these pathogens from the sentinel site surveillance initiative.

2. Exposure Assessment

Rarely can actual exposure to a specific strain of foodborne pathogen be quantified with certainty in foodborne disease outbreaks. Microbes in food are known to be non-homogeneously distributed, imposing additional uncertainty due to sampling error upon the analytical variability of the methods for detection and quantification of microbes in foods. The outbreak strain may or may not be detected in the feces of diarrheal cases or in leftovers or companion samples from suspected lots. The levels detected in leftovers or companion samples from the same lot of food may or may not be representative of the serving that was prepared and consumed since the microbial numbers vary with time and temperature conditions and the initial microbial populations. The amount of the serving consumed may not be known.

The FSIS baseline studies provide data on occurrence of pathogens (likelihood) and levels (magnitude) in uncooked meat and poultry products at slaughter and raw ground processing. Data for likelihood and magnitude of pathogens in the distribution, preparation, and consumption phases of the farm-to-fork continuum of food production are sparse. Predictive microbiology models may be the most cost-effective method to deduce possible exposure scenarios in meat and poultry beyond the slaughter phase that may result in foodborne illness. The likelihood that the selected scenarios of improper cooking and abuse actually occur among U.S. consumers may not be measurable, but the scenarios may be useful in modification of behaviors that pose increased risk to consumers.

3. Dose-Response Assessment

The relationship between the dose of a pathogen and response in the host, when known, can vary greatly for foodborne pathogens. Human feeding studies with foodborne pathogens were largely conducted several decades ago with small numbers of healthy adult males. One study reported both ill and asymptomatic volunteers who had consumed up to 1,000,000,000 pathogenic *Salmonella.* Outbreak data for other *Salmonella* serotypes in food vehicles suggest a range of infective doses from one cell to 1,000,000,000,000 cells (Blaser & Newman, 1982). Fatty food vehicles, including some meat and

poultry products, are thought to protect enteropathogens from stomach acids and digestive enzymes that might otherwise reduce the dose to the intestinal tract and reduce the likelihood of disease. The effects of competition of the pathogen with the large indigenous microbial populations in food (ICMSF, 1980) and in the human gastrointestinal tract (Rolfe, 1991) may reduce the likelihood and/or the severity of foodborne disease.

Even carefully controlled volunteer feeding experiments at doses up to one billion organisms per volunteer have shown variability in the infectious dose of one pathogen for individuals within a group of seemingly healthy, young adults. Extrapolation of empirical models of effects at high doses to low doses typical of properly handled food may or may not be appropriate. The dose-response curve for healthy adult males may not be useful in estimating dose-response relationships for the general population or sensitive sub-populations. The data available from human feeding studies were generated from very few species and strains of bacterial pathogens, excluding *E. coli* 0157:H7. Dose-response modeling is crucial to microbial and chemical risk assessments. FSIS believes that application of dose-response models in food safety regulation requires careful examination of the validity of the assumptions and inputs of the model and of the plausibility of the model as a descriptor of foodborne disease processes.

4. Risk Characterization

The integration of exposure and dose-response models is expected in risk characterization, along with sensitivity and uncertainty analyses (Burmaster & Anderson, 1995) for the risk model. Perhaps of greater significance than the numerical estimate of risk is the uncertainty associated with the estimate. A fully developed risk characterization would include risk estimates and sensitivity/uncertainty analyses for alternative models and assumptions. FSIS is collaborating with scientists in academia, the Agricultural Research Service, the Animal & Plant Health Inspection Service, the Economic Research Service, and the Office of Risk Assessment and Cost Benefit Analysis to develop and validate a risk assessment model for a single pathogen in a single meat product. This model may be modified for other specific pathogens of concern. The expectation of a generic model for all foodborne disease agents in all products does not appear promising based on differences in pathogenesis of bacterial species and strains and in human sensitivity and pathology.

FSIS continues to evaluate new information on foodborne pathogens and on risk assessment methods and tools in accordance with the FSIS public health mission. The NAS Report, the CAST Report and the 1995 Conference recognize HACCP as a system to reduce the likelihood of foodborne illness. The CAST Task Force also concluded that ''the efficacy of a HACCP system depends on the rigor and consistency with which it is designed and implemented and the use of (a) critical control point(s) that will control pathogens.''

D. FSIS Data Initiatives

The 1994 report, ''Foodborne Pathogens: Risks and Consequences, CAST Task Force Report No. 122, September 1994'' concluded that ''a comprehensive system of assessing the risks of human illness from microbial pathogens in the food supply has yet to be devised.'' They cited the limitations of the current food safety information database and the difficulty in accumulating dose response and minimum infective dose data. A recent multidisciplinary conference, ''Tracking Foodborne Pathogens from Farm-to-Table, Data Needs to Evaluate Control Options'', carefully reviewed current databases and confirmed limitations outlined in the CAST Task Force report.

FSIS has established initiatives to improve the quality and quantity of data in two major areas. First, FSIS is working with the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to establish an active sentinel site surveillance system for the major causes of foodborne illness. This project is designed to accumulate data on the incidence of foodborne illness by pathogen and by food.

Second, the Agency has been developing baseline data for pathogen levels on major food animal species at the time of slaughter. The baseline data will allow the Agency to detect changes in the overall nation-wide pathogen levels. The National Baseline program was initiated in 1992 to provide information on the type and level of microbiological contamination on raw products under Federal inspection. Each sample collected is analyzed for nine microorganisms or groups of organisms. Microbiological baseline data are now available for steers and heifers, cows and bulls, and broiler chickens.

If sufficient data on both pathogen levels and foodborne disease epidemiology result from current and future initiatives, FSIS should be able to develop models showing how these two variables are related for different pathogens. These models should then permit/facilitate a quantitative estimate of risk. Such data are essential for FSIS to evaluate the effect of control measures on both pathogens levels and on foodborne illness.

E. ARS Food Safety Research Program

The Agricultural Research Service (ARS) administers a food safety research program that is currently funded at approximately $45 million per year. This program addresses problems in four different areas; pathogen reduction, mycotoxins, residues, and natural toxins. The reduction of microbial pathogens in food products of animal origin is the most pressing food safety problem today. Consequently, the pathogen reduction component is the largest of the four areas and is currently funded at $18.2 million annually. The ARS research in pathogen reduction addresses both preharvest and animal production, and post harvest problem areas, with approximately equal funding for each.

Ongoing ARS research will help FSIS improve its capability for performing quantitative risk assessment in the area of foodborne pathogens or improve the ability to predict the effectiveness of new pathogen reduction technologies. Ongoing projects include the modeling of bacterial growth or thermal death times which will help set standards for meat and poultry products. Ongoing projects will also provide new laboratory screening or confirmatory methods. Other projects provide and/or evaluate technology and management methods which can help producers achieve lower contamination levels in animals presented for slaughter, such as vaccines or competitive bacterial cultures to prevent pathogens in live animals. There are also technology and management methods for use in slaughter and processing establishments, such as, organic acids for use in carcass sanitation, improvements to the feather picking operation for poultry, washing of trailers to reduce microbiological contamination, and establishment of guidelines on the microbiological safety of recycling cooling solutions for ready-to-cook meat and poultry products. In many cases the research may provide the scientific basis for developing and improving technology, for example, the nature of bacterial attachment to various meat surfaces.

FSIS can and does forward very specific research requests to ARS. In preparation for this final rule, FSIS requested that ARS compare the results

from different microbial sample collection techniques, sponging versus excision at one versus three carcass sites. These studies are currently being conducted on both cow/bull and market hog carcasses. There are other specific ARS projects that will help provide the scientific basis for HACCP through risk assessment, predictive microbiology, and pathogen reduction interventions for several different bacterial pathogens which must be controlled to assure the safety of meat and poultry.

These projects include: (1) Development of models to predict the growth rates, survival times, and thermal death rates for microbial pathogens potentially present in foods, including meat and meat products. (Microbiological modeling is time consuming and expensive because it requires that the data be quantified, that is, that numbers of bacteria are obtained, rather just the knowledge of the presence or absence of a pathogen under the conditions of the test.) The microorganisms being studied include *E. coli* O157:H7, *Listeria monocytogenes,* and *Salmonella.* These models are written into personal computer software that gives FSIS a readily useable tool to help evaluate proposed meat processes and assess out-of-process events. Refining predictive models has the goal of linking an entire process from raw ingredients to distribution of finished product. A specific project is to model the survival of *E. coli* O157:H7 during the manufacture of uncooked, fermented meat products. Using the information obtained, ARS will closely collaborate with other USDA agencies to develop strategies for risk reduction using the various processing techniques, and to create risk assessment models.

(2) Modeling studies to predict the thermal inactivation of spore-forming and non-spore-forming bacterial pathogens of both cooked and ready-to-eat products. These studies will be extended to the cooling of these products to ensure that there is no potential for growth of *Clostridium botulinum* and *C. perfringens.*

(3) Determination of the long-term effects (21 days of storage at refrigerated temperatures) of organic acid treatment of red meat on some key pathogens (*E. coli* O157:H7, *Listeria,* and *Clostridium*), as well as on spoilage bacteria (mesophilic aerobes, lactic acid bacteria, and pseudomonads).

(4) Delineation of the parameters affecting the antibacterial activity of organic acids. These include tissue type (pre-rigor, post-rigor, frozen post rigor), inoculum type (pure culture or inoculated feces), inoculum level and the temperature of spray wash at meat surface. These results should clarify inconsistent reports on antibacterial activity of organic acids and also define optimum conditions to maximize the antibacterial activity of organic acids.

(5) The correlation of the *Campylobacter* levels in broilers from the chill tank with their *Campylobacter* levels during production.

F. Analysis of Comments on Public Health Benefits

There were many comments on the methodology used to estimate public health benefits in the preliminary analysis. This methodology used a series of estimates or assumptions based on incomplete data related to the six following areas:

- Incidence of foodborne illness
- Cost of foodborne illness
- Percentage of foodborne illness and cost of foodborne illness attributable to meat and poultry products
- Pathogens addressed by the rule
- Effectiveness of rule in reducing pathogens
- Estimated reduction in cost of foodborne illness related to reduction of pathogens

To facilitate discussion of the issues raised in comments, the issues are addressed organized by these six areas.

1. Incidence of Foodborne Illness

Table 4 presents the most recent estimates on the incidence of illness and death for selected pathogens along with the latest estimates on the percentage of illness and death which is foodborne. As discussed in the preliminary RIA, Table 4 includes the ''best estimates'' when precise data are not available. Many of these estimates are based on the landmark CDC study by Bennett, Holmberg, Rogers, and Solomon, published in 1987, which used CDC surveillance and outbreak data, published reports, and expert opinion to estimate the overall incidence and case-fatality ratio for all infectious and parasitic diseases. Estimates on the foodborne percentage of illness and death for bacteria in Table 4 are all based on CDC data. The resulting estimates for the number of foodborne cases and deaths are presented in the second and third columns of Table 5.

The benefits for the preliminary analysis and this final RIA are calculated for the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli, E. coli* O157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes.* FSIS believes that these four pathogens can be reduced through improved process control in the manufacturing sector.

Although *Clostridium perfringens* and *Staphylococcus aureus* also cause a significant number of foodborne illnesses, they are not included in the benefits analysis because it is not clear that the HACCP-based regulatory program, which focuses on federally inspected processing, will significantly affect the incidence of disease caused by these organisms. *Staphylococcus aureus* usually enters the food chain through food handlers in restaurants and other commercial kitchens. Although *C. perfringens* may enter the food chain through the slaughter process, it is so ubiquitous in the environment that FSIS will not assume that controls at slaughter will be effective against this pathogen.

One commenter questioned why the Agency has not addressed the public health problem of toxoplasmosis given the Table 5 estimate of $2.7 billion in annual costs. FSIS believes that while process control may help decrease the spread of cysts during boning and cutting operations, most of the *Toxoplasma gondi* cysts are internal to infective muscle tissues and are not addressable by process control. Therefore, FSIS is making the more conservative assumption to exclude this pathogen in the benefits estimate of disease averted.

Many comments suggested that the large range in the illness incidence estimates demonstrates that there are insufficient data on which to base a new regulatory program. Historically, the lack of quantitative data on benefits and specific health risks have meant that health and safety regulations have required decisionmaking under uncertainty and have required the decisionmaker to balance the need to act with the need for additional or improved data. Compared to such issues as whether a chemical is a potential human carcinogen or whether low levels of air pollutants cause adverse health effects, the health effects of enteric pathogens are relatively well documented. If the pathogens enter the food supply, they do, under certain conditions, cause foodborne illness. If their presence can be prevented, no amount of temperature abuse, mishandling or undercooking can lead to foodborne illness.

The Agency believes that the existing estimates on foodborne illness are adequate to conclude that a substantial and intolerable public health problem exists. Furthermore, existing estimates are appropriate for developing estimates on the cost of foodborne illness attributable to meat and poultry. The

Agency notes that similar estimates on the incidence of foodborne illness have been published by scientists from ERS in peer-reviewed journal articles (see footnotes to Table 5) and by the 1994 CAST Task Force.

The above statement that Table 4 includes the most recent estimates of the incidence of illness and death requires further explanation in the case of *Listeria monocytogenes.* The estimates of 1,795–1,860 cases of listeriosis and 445–510 deaths are the ones used in the latest cost of illness study conducted by ERS. ERS is in the process of publishing a comprehensive documentation for the estimates of cost of illness for 1993. In their draft document they acknowledge that the estimate for listeriosis cases originates from an extrapolation to the U.S. population of incidence data from a CDC-conducted surveillance study of six geographic regions in 1986 and 1987 (Gellin *et al.* 1987). They also note that (Tappero *et al.* 1995) found that the incidence of listeriosis has decreased since the 1960's and that projections from the surveillance data suggest that there were 1,092 listeriosis cases and 248 deaths in 1993. ERS did not modify their cost of illness estimates because Tappero *et al.,* was published after their analysis was concluded.

FSIS considered modifying the cost of illness estimates for this final analysis but decided to use the estimates in Tables 4 and 5 because (1) They are the figures that will appear in the upcoming ERS publication and, (2) updating the listeriosis estimates would have minimal impact on the overall cost of illness estimates. Considering the overall range and uncertainties involved in the cost of illness estimates, the change in listeriosis estimates has negligible impact on the regulatory analysis information conveyed through the potential benefits estimate.

The Agency also recognizes that in using the 1993 estimates for incidence of foodborne illness, the benefits analysis has not accounted for possible reductions in foodborne illness attributable to the rule that mandated safe handling statements on labeling of raw meat and poultry products. The rule mandating safe handling instructions became effective on May 27, 1994. Thus, it can be argued that the incidence of foodborne illness for 1994 through the present should reflect the effectiveness of the 1994 labeling requirement in reducing the incidence of illness.

FSIS is not aware of any quantitative evaluation of the effectiveness of safe handling labeling. Two recent surveys indicate a high level of awareness, but these surveys do not contain findings that can be translated into changes in consumer behavior. A recent Associated Press poll found that 9 in 10 Americans say they follow the safe-handling instructions. This poll, conducted in April 1996, included 1,019 randomly selected adults. This was a telephone survey conducted by ICR Survey Research Group. A November 1995 survey conducted by Wegman Food Markets in Buffalo, Rochester, and Syracuse found that 67.9 percent of respondents indicated they had read the safe handling information. The Wegman's survey found that most household meat preparers rely on color of meat or clarity of juices rather than temperature to determine when meat has been cooked thoroughly.

In this analysis, FSIS has not attempted to adjust the 1993 baseline to account for safe handling labeling. The potential effect of the 1994 regulation is one of many factors that could be affecting the current incidence or cost of illness. A May 1996 GAO study on foodborne illness notes that food safety and public health officials believe that the risk of foodborne illness is increasing. If they are correct, the 1994 labeling rule may be slowing the growth rather than reducing the absolute level.

There are many other factors that could have been incorporated into the baseline for the analysis such as population growth and increases in the cost of medical care. FSIS believes that attempts to adjust the cost of illness baseline to account for factors such as inflation, possible increases in foodborne illness due to behavior change or population increases, and possible decreases due to inventions such as safe handling labels are more likely to be misleading than informative given the level of uncertainly and wide range in existing estimates.

2. Cost of Foodborne Illness

The fourth column of Table 5 shows that the 1993 estimated cost of foodborne illness by pathogen or parasite was between $5.6 and $9.4 billion. These cost of illness estimates have been developed by ERS in conjunction with CDC over the past 15 years. As indicated in footnotes to Table 5, the results of that work have been frequently published in peer-reviewed journals.

There were only a few public comments on the proposed rule which addressed the methodology used for estimating the cost of foodborne illness. Some comments argued that the public health benefit estimates are low because of the low value-of-life factor used in the estimates for the cost of foodborne illness.

ERS intentionally used a conservative method to estimate the value of a statistical life (VOSL) acknowledging the controversy over valuing lives. ERS used Landefeld and Seskin's VOSL estimates and recognizes that the cost of illness estimates would be substantially higher if they used alternative methods. For example, Viscusi (1993) summarized the results of 24 principal labor market studies and found that the majority of the VOSL estimates lie between $3 million and $7 million per life. A survey of the wage-risk premium literature on the willingness to pay to prevent death concluded that reasonably consistent estimates of the value of a statistical life range from $1.6 million to $6.5 million dollars (1986 dollars) (Fisher et al. 1989). Updated to 1993 dollars using the change in average weekly earnings, Viscusi's range becomes $3.2 million to $7.6 million per VOSL and Fisher's range becomes $2.0 million to $10.4 million dollars for each statistical-life lost. Viscusi and the Fisher estimates are greater than the highest Landefeld-Seskin (LS) VOSL estimate of $1,584,605 in 1993 dollars (estimate for a 22 year old).

TABLE 4.—SOURCES OF DATA FOR SELECTED PATHOGENS, 1993

Pathogen	Estimated number of cases	Estimated number of deaths	Source(s) for case and death estimates	Percent foodborne	Source
Bacteria:					
Campylobacter jejuni or coli	2,500,000	200–730	Tauxe	55–70	Tauxe et al.
Clostridium perfringens	10,000	100	Bennett et al.	100	Bennett et al.
Escherichia coli O157:H7	10,000–20,000	200–500	AGA Conference	80	AGA Conf./CDC.
Listeria monocytogenes	1,795–1,860	445–510	Roberts and Pinner	85–95	Schuchat.

TABLE 4.—SOURCES OF DATA FOR SELECTED PATHOGENS, 1993—Continued

Pathogen	Estimated number of cases	Estimated number of deaths	Source(s) for case and death estimates	Percent foodborne	Source
Salmonella	800,000–4,000,000	800–4,000	Helmick et al./Bennett et al.	87–96	Bennett et al./Tauxe & Blake.
Staphylococcus aureus	8,900,000	7,120	Bennett et al	17	Bennett et al
Parasite:					
Toxoplasma gondii	4,111	82	Roberts et al.	50	Roberts et al.

Sources: American Gastroenterological Association Consensus Conference on E. coli O157:H7, Washington, DC, July 11–13, 1994. Bennett, J.V., S.D. Holmberg, M.F. Rogers, and S.L. Solomon. 1987. ''Infectious and Parasitic Diseases,'' In R.W. Amler and H.B. Dull (Eds.) *Closing the Gap: The Burden of Unnecessary Illness.* Oxford University Press, New York. Helmick, C.G., P.M. Griffin, D.G. Addiss, R.V. Tauxe, and D.D. Juranek. 1994. ''Infectious Diarrheas.'' In: Everheart, JE, ed. *Digestive Diseases in the United States: Epidemiology and Impact.* USDHHS, NIH, NIDDKD, NIH Pub. No. 94–1447, pp. 85–123, Wash, DC: USGPO.

Roberts, T., K.D. Murrell, and S. Marks. 1994. ''Economic Losses Caused by Foodborne Parasitic Diseases,'' *Parasitology Today.* vol. 10, no. 11: 419–423.

Schuchat, Anne, CDC, personal communication with T. Roberts at the FDA Science Forum on Regulatory Sciences, Washington, DC, September 29, 1994.

Tauxe, R.V., ''Epidemiology of Campylobacter jejuni infections in the United States and other Industrialized Nations.'' In Nachamkin, Blaser, Tompkins, ed. *Campylobacter jejuni: Current Status and Future Trends,* 1994, chapter 2, pages 9–19. Tauxe, R.V. and P.A. Blake, 1992. ''Salmonellosis'' Chap. 12. In: Public Health & Preventative Medicine, 13th ed. (Eds: Last JM: Wallace RB; Barrett-Conner E) Appleton & Lange, Norwalk, Connecticut, 266–268.

Tauxe, R.V., N. Hargrett-Bean, C.M. Patton, and I.K. Wachsmuth. 1988. ''Campylobacter Isolates in the United States, 1982–1986,'' *Morbidity and Mortality Weekly Report,* vol 31, no. SS–2: pages 1–14.

TABLE 5.—MEDICAL COSTS AND PRODUCTIVITY LOSSES ESTIMATED FOR SELECTED FOODBORNE PATHOGENS, 1993

Pathogen	Foodborne illness		Foodborne* costs (bil $)	Percent from meat/poultry (%)	Meat/poultry related		Total costs* meat/poultry (bil $)
	Est. No. of cases	Est. No. deaths			Est. No. of cases	Est. No. deaths	
Bacteria:							
Campylobacter jejuni or coli	1,375,000–1,750,000	110–511	0.6–1.0	75	1,031,250–1,312,500	83–383	0.5–0.8
Clostridium perfringens**	10,000	100	0.1	50	5,000	50	0.1
Escherichia coli 0157:H7	8,000–16,000	160–400	0.2–0.6	75	6,000–12,000	120–300	0.2–0.5
Listeria monocytogenes	1,526–1,767	378–485	0.2–0.3	50	763–884	189–243	0.1–0.2
Salmonella	696,000–3,840,000	696–3,840	0.6–3.5	50–75	348,000–2,880,000	348–2,880	0.3–2.6
Staphylococcus aureus**	1,513,000	1,210	1.2	50	756,500	605	0.6
Subtotal	3,603,526–7,130,767	2,654–6,546	2.9–6.7	N/A	2,147,513–4,966,884	1,395–4,461	1.8–4.8
Parasite:							
Toxoplasma gondii	2,056	41	2.7	100	2,056	41	2.7
Total	3,605,582–7,132,823	2,695–6,587	5.6–9.4	N/A	2,149,569–4,968,940	1,436–4,502	4.5–7.5

Source: ERS, 1993

*Column rounded to one decimal place.

**Roberts' rough approximation of costs in ''Human Illness Costs of Foodborne Bacteria'', *Amer. J. of Agricultural Economics*, vol. 71, no. 2 (May 1989) pp. 468–474 were updated to 1993 dollars using the Consumer Price Index (all items, annual average). Cost estimates for other pathogens are more detailed, see the following for a discussion of the methodology:

listeriosis—Roberts, Tanya and Robert Pinner, ''Economic Impact of Disease Caused by *Listeria monocytogenes*'' in *Foodborne Listeriosis* ed. by A.J. Miller, J.L. Smith, and G.A. Somkuti. Elsevier Science: Amsterdam, The Netherlands, 1990, pp. 137–149,

E. coli O157:H7—Roberts, T. and Marks, S., ''*E. coli* O157:H7 Ranks as the Fourth Most Costly Foodborne Disease,'' *FoodReview*, USDA/ERS, Sept-Dec 1993, pp. 51–59.

salmonellosis—Roberts, Tanya, ''Salmonellosis Control: Estimated Economic Costs,'' *Poultry Science*. Vol. 67 (June 1988) pp. 936–943,

campylobacteriosis—Morrison, Rosanna Mentzer, Tanya Roberts, and Lawrence Witucki, ''Irradiation of U.S. Poultry—Benefits, Costs, and Export Potential, *FoodReview*, Vol. 15, No. 3, October-December 1992, pp. 16–21, congenital toxoplasmosis—Roberts, T., K.D. Murrell, and S. Marks. 1944. ''Economic Losses Caused by Foodborne Parasitic Diseases,'' *Parasitology Today.* vol. 10, no. 11: 419–423; and Roberts, Tanya and J.K. Frenkel, ''Estimating Income Losses and Other Preventable Costs Caused by Congenital Toxoplasmosis in People in the United States,'' *J. of the Amer. Veterinary Medical Assoc.*, vol. 196, no. 2 (January 15, 1990) pages 249–256.

N/A indicates item is not-applicable.

ERS is currently working on a sensitivity analysis for their cost of illness estimates for foodborne illness. The sensitivity analysis replaces the LS VOSL estimates with estimates found in the literature on wage-risk studies. Preliminary findings show that the estimates of the total cost of foodborne illness will increase greatly when these higher VOSL estimates are used.

FSIS considers that the existing conservative estimates are appropriate considering the controversy and uncertainty. The conservative estimates are more than sufficient to justify the

final rule implementing a new HACCP-based regulatory program for meat and poultry. This final RIA uses the cost of illness estimates shown in Table 5.

Another comment stated that the cost of illness estimates are low because they do not account for increases in productivity. In response, the Agency notes that ERS used Landefeld and Seskin's estimates for the value of a statistical life, and those estimates do include an estimated 1% annual increase in productivity.

One commenter suggested that a methodology based on earning power may overestimate the value of life where many deaths from foodborne illness are the very elderly, the immunocompromised and the terminally ill. This commenter also noted that while all deaths are tragic, from a strictly economic standpoint many of these tragic cases have little or no productivity left and in fact are utilizing resources at the rate of $3,000 to $12,000 or more dollars per month of maintenance.

The cost of illness methodology used by ERS does account for the fact that older individuals have lower remaining earning power than younger individuals. This difference was taken into account when estimating the costs of lost productivity for *salmonellosis* patients. Different Landefeld and Seskin estimates of the values of statistical life were used for the different age categories. The methodology used U.S. death certificate data to estimate that the average age for patients who die from salmonellosis is over 65 years. The concept of a statistical value of life accounts for the fact that older individuals may continue to work or be retired or be patients under long term health care.

3. Percentage of Foodborne Illness and Cost of Foodborne Illness Attributable to Meat and Poultry

The fifth column of Table 5 includes estimates on the percentage of foodborne illness attributable to meat and poultry products. A separate estimate has been developed for each pathogen. These estimates are based on outbreak data reported under the CDC Foodborne Disease Outbreak Surveillance System and on data from community-based and other epidemiologic studies. Major data sources are cited in the preamble to the final rule. An assumption is made in this analysis that the source of foodborne pathogens, i.e., meat and poultry versus dairy products, seafood, vegetable, etc., has no effect on the cost of illness. The Department is not aware of any data indicating that the severity of foodborne illness cases varies by source of pathogens.

Comments noted that the Department had increased the percentage of foodborne illness attributable to meat and poultry from the earlier rulemaking for safe handling labels. One commenter stated that the Department has not revealed any new information which would support such an increase.

At this time, data on incidence of foodborne illnesses and the percentage of cases attributable to different food items are limited. Estimates by pathogen have been made by experts at CDC and USDA, based on a variety of studies. However, these are, indeed, estimates: FSIS does not have exact numbers. The estimates in the 1993 Federal Register document were relatively crude, assuming that 100% of *Campylobacter* and *E. coli* O157:H7 cases, 96% of *Salmonella* cases, and 85% of *Listeria* cases were foodborne, and that, for all bacterial pathogens, a flat 50% of foodborne cases were attributable to meat and poultry. The 1995 document looked at the numbers in a somewhat more sophisticated way, evaluating each pathogen individually and, where appropriate, giving ranges for, first, percentage of cases which were foodborne, and, secondly, percentage of cases which were attributable to meat and poultry. Nonetheless, when all of the various percentages are multiplied out, estimates of total cases attributable to meat and poultry were remarkably similar, as shown below in Table 6.

TABLE 6.—PERCENTAGE OF FOODBORNE ILLNESS ATTRIBUTABLE TO MEAT AND POULTRY

Pathogen	Percentage of total cases attributed to meat and poultry [a] 1993 (percent)	Percentage of total cases attributed to meat and poultry, 1995 (percent)	Estimated total cases, 1993	Estimated total cases, 1995
Campylobacter	50	41–53	1,050,000	1,031,250–1,312,500
Salmonella	48	43–72	921,600	348,000–2,880,000
E. coli O157:H7	50	60	3,834–10,22	46,000–12,000
Listeria	43	43–48	649–672	763–884

[a] Reflects percentage of foodborne multiplied by percentage attributable to meat and poultry.

Most other comments related to the estimates on the percentage of foodborne illness attributable to poultry. Comments questioned the high incidence of poultry-related foodborne illness when even, as a commenter asserted, public health authorities tell consumers that the problem with poultry meat is not due to consumption because poultry is cooked. Comments questioned whether cross-contamination in the kitchens could possibly generate such high levels of foodborne illness. Related comments suggested that if cross-contamination was such a serious problem, the data would show more outbreaks and fewer single cases. Other comments suggested that the cost of salmonellosis attributed to poultry was high because of the high incidence of *Salmonella enteritidis* in eggs and requested that the Agency exclude any foodborne illness costs associated with eggs, because those issues are outside the scope of this rulemaking. Another comment cited an Australian finding that the *Campylobacter* strains that infect chickens are not the strains that primarily infect humans.

The Department agrees that undercooked poultry is not a primary cause of foodborne illness. The preamble to the proposal stated that the majority of salmonellosis results from cross-contamination. The best available estimates for foodborne illness do suggest that a high incidence of illness is attributable to cross-contamination in kitchens—both household kitchens and food-service establishments.

The comment suggesting that cross-contamination would have led to more outbreaks makes sense, if the available estimates on incidence were heavily

based on outbreak data. However, as mentioned in the proposal, it is widely recognized that CDC outbreak data do not provide accurate estimates of foodborne disease incidence. The outbreak data are more useful in identifying factors that lead to illness and have been used to estimate proportions of illness attributable to specific food groups. They do not play a major role in the overall incidence estimates. The existing incidence estimates are for total cases including both individual cases and multiple cases. The methodology used does not distinguish between outbreaks and single cases. Just as there are unreported individual cases of foodborne illness, there are unreported cases where entire households or portions of households experience foodborne illness due to cross-contamination in household kitchens. As discussed above, the estimates of foodborne illness were derived from both CDC outbreak data and community-based epidemiologic studies.

The outbreak data (two or more individuals ill from the same source) are compiled by CDC from reports that are voluntarily submitted from state and local health authorities. The laboratory reporting system for *Salmonella* only captures information on those cases where a patient sees a doctor, the doctor collects a stool culture and sends the culture to a participating laboratory and the laboratory can perform the specific diagnostic test. The estimates for overall disease incidence are derived using both databases plus data collected from population-based studies in specific geographic areas. The current (initiative) collaborative surveillance project should improve the estimates in the future.

The comment referring to the Australian finding is referring to an article by Korolik, et al, published in the May 1995 issue of the Journal of Clinical Microbiology, entitled, ''Differentiation of *Campylobacter jejuni* and *Campylobacter coli* strains by Using Restriction Endonuclease DNA Profiles and DNA Fragment Polymorphisms.'' The study was undertaken to determine if DNA fingerprinting technologies could identify strains of *Campylobacter* in chickens that cause disease in humans.

FSIS reviewed the article and concluded that the study did not refute U.S. epidemiologic studies showing that approximately 50% of human *Campylobacter* infections are due to poultry. To confirm FSIS's interpretation of the study, a staff member contacted the author, Dr. Victoria Korolik, in Australia. She confirmed that her study does not shed doubt on the role of poultry in human *Campylobacter* infections.

4. Pathogens Addressed by the Rule

While the proposed rule indicated that HACCP systems will be designed to control all public health hazards, the preliminary benefits analysis assumed that the primary benefits will come from controlling the three most common enteric pathogens of animal origin: *Campylobacter jejuni/coli*, *E. coli* O157:H7, *Salmonella* and one environmental pathogen *Listeria monocytogenes*. Two other pathogens—*Clostridium perfringens* and *Staphylococcus aureus* primarily become or create hazards in meat and poultry products as prepared in restaurants, other commercial kitchens, and in homes. Consequently, the proposed regulatory program, which focuses on the manufacturing sector, will not significantly affect the presence of these organisms on meat and poultry products.

The public comments did not address the assumption that the proposed rule would have the most impact on the four pathogens identified above and that benefits would be most appropriately discussed in terms of reducing the level of these pathogens. This final RIA will continue to assume that the HACCP-based regulatory program will have the most impact on the four pathogens identified in the preliminary analysis.

The preliminary benefits analysis also included an assumption concerning the percentage of the four pathogens that contaminate the meat and poultry supply at inspected establishments or grow from contamination that occurs at inspected locations. Based on the expert judgment of FSIS microbiologists, the preliminary benefit analysis assumed that 90 percent of the four pathogens result from contamination that occurs at inspected establishments.

The public comments did not directly address the estimate that slaughter and processing establishments are the source of 90 percent of enteric pathogen contamination. There were, however, a large number of comments that cited studies or estimates that show or indicate that the majority of foodborne illness can be attributed to improper cooking, recontamination and other mishandling and abuse in the food service and home environment. Many comments cited data presented in the 1994 CAST Report which ''demonstrated'' that only 6.9 percent of outbreaks were ''attributable'' to the food processing establishments. Other comments referred to ''a well-recognized fact that 97 percent of the problems with foodborne illness occur outside the realm of state and federal inspection.'' Other comments attributed the 97 percent figure to a Special Report by the American Association of Meat Processors. These types of comments were presented in a manner indicating that the commenters believe that the data attributing ''cause'' to the food service or home environment directly contradicts the Agency's estimate that inspected establishments are the source of 90 percent of the four pathogens addressed by this rule.

In response, the Agency points out that the studies cited by commenters concluding that high percentages of foodborne illness are attributable to factors such as temperature abuse and mishandling do not conflict with either the assumption that slaughter and processing establishments are the source of 90 percent of enteric pathogen contamination or the assumption discussed later concerning the effectiveness of HACCP in reducing that contamination. Occurrence of foodborne disease is a multi-step process. The first, and critical, step is the introduction of a pathogen into or onto the raw product. If a pathogen is present, then subsequent temperature abuse or mishandling may permit bacterial counts to increase to levels which increase the likelihood that illness will occur; mishandling may result in cross-contamination of other foods which are not cooked before being eaten; or improper cooking may not kill all pathogenic bacteria present in the product. In these instances, it may be said that the illness was ''caused'' by improper handling. However, disease would not have occurred if the pathogen had not been present on the raw product in the first place.

The CAST study included a table showing factors contributing to the occurrence of 1,080 outbreaks occurring from 1973 to 1982. That table consisted of data from the CDC national foodborne disease surveillance system that was published in an article in the Journal of Food Protection by Frank L. Bryan in 1988. The CAST study and journal articles use terminology like ''factors that contribute'' and address the location or type of employee/consumer where any mishandling or mistreatment of food occurred. The focus of these studies is to enhance our understanding of the sequences of events and behaviors that lead to foodborne illness since behavioral modification for the food preparer and consumer at the end of the food chain may have the greatest impact on the incidence of foodborne disease. Many of the comments are written in a manner that blurs the distinction

between factors in the kitchen that may permit an outbreak to occur from slaughter-origin contamination and those that would have caused an outbreak despite the absence of contamination of the raw ingredients.

The comments referring to the CAST study or directly to CDC estimates have not interpreted the Foodborne Disease Outbreak Surveillance Data correctly. The standard CDC foodborne disease outbreak report form does not include a question about whether the food processing industry was involved, and while many foodborne outbreaks have a chain of causation, investigators may differ in their assessment of the point or points in the chain to which primary responsibility for occurrence of the outbreak should be assigned.

The Bryan article used for the CAST study had the following summary concerning the role of food processing establishments: ''Many of the animals that enter abattoirs are either infected or contaminated with foodborne pathogens and further spread occurs during processing. Hence, abattoirs and raw-product processing establishments must accept some of the blame of spreading salmonellae and other pathogens to many carcasses and pieces of meat. These products are major sources of pathogens for food-service establishments and homes where further abuse (e.g., inadequate cooking or cross contamination) leads to outbreaks of foodborne illness.''

The comments have not provided any basis for changing the expert judgment of FSIS microbiologists that inspected establishments are the source of 90 percent of the four pathogens addressed by the final rule. This final benefits analysis is based on this assumption.

5. Effectiveness of the Rule in Reducing Pathogens

In accordance with the assumption that meat and poultry establishments are the source of 90 percent of the four pathogens addressed by the rule, the preliminary analysis calculated the benefits under a scenario where the proposed rule would eliminate essentially 100 percent of those pathogens that enter the meat and poultry supply at inspected processing establishments. In other words, for the preliminary analysis, FSIS calculated an estimate of maximum benefits by assuming the rule would eliminate 100 percent of the 90 percent.

By assuming this scenario, FSIS was not predicting that it believed that the rule would result in elimination of 100 percent of those pathogens in the manufacturing sector. Rather, the Agency was acknowledging that it has responsibility for having a food safety objective that recognizes the scope of the problem and attempts to reduce pathogens in that sector as much as possible, since without pathogens, no amount of subsequent abuse would result in foodborne illness.

By presenting a sensitivity analysis in the proposal, FSIS intended to clarify that the benefit estimates were a maximum and not a prediction of what is likely to happen. The distinction was unclear to many commenters who expressed doubt that the proposed HACCP program would result in a 90 percent reduction in pathogens. A large number of comments on the potential effectiveness of HACCP programs contrasted the FSIS estimates with those contained in the recent study by the Institute of Food Science and Engineering, Texas A&M University, titled ''Reforming Meat and Poultry Inspection: Impacts of Policy Options,'' (hereafter referred to as the IFSE study). Both FSIS and IFSE estimates are useful as assumptions rather than as quantitative predictions of potential effectiveness of HACCP.

The ISFE study examined four policy options for addressing pathogens in the meat and poultry supply. One option called for mandatory HACCP for inspected slaughter and processing establishments and estimated that mandatory HACCP in inspected establishments would produce a 20 percent reduction in pathogens. The difference in the FSIS and IFSE estimates is not based on data but on assumptions for different ''HACCP'' scenarios.

The HACCP program scenario considered in the IFSE study did not assume a mandatory pathogen reduction performance standard. Requiring process control without a standard could lead to processes that are well controlled at unacceptable pathogen levels. The Agency would agree that such a situation would result in less pathogen reduction. FSIS believes that a standard is necessary to encourage innovation and provide the impetus for continuing improvement and increasing effectiveness. In estimating effectiveness, the IFSE study noted that ''with experience and additional research, it is possible that higher levels of reduction in pathogens could be achieved * * *''.

Another major difference between the two program scenarios is that the IFSE program does not include a prerequisite requirement for SOP's. SOP's could cover potential sources of enteric and environmental pathogens that are not be covered under a HACCP plan. However, as discussed in Section I, this analysis discusses benefits of SOP's in terms of increased productivity for inspection resources and clarity of responsibilities.

Several comments refer to the IFSE estimates as being more objective or ''scientific'' than those in the Agency's analysis. The IFSE authors characterize their own effectiveness estimates as ''the consensus judgment of the task force'' or ''the most reasonable expectation.'' The IFSE estimates are judgments, as are the Agency's estimates.

A general comment related to the effectiveness issue stated that while HACCP remains an interesting theoretical concept, it is still only a concept that has never been tested on a meaningful scale under actual meat establishment conditions, and never proven to significantly improve the microbial quality of the finished product. Although HACCP has been tested in food processing establishments to the satisfaction of scientists, food technologists, and industry management to produce safe food, the Agency recognizes that the potential effectiveness of HACCP in reducing pathogens within a regulatory framework is unknown at the present time. FSIS conducted a pilot HACCP study in nine establishments from 1991 to 1993. Findings regarding pathogen reduction effectiveness were inconclusive. FSIS did not receive any data during the comment period from establishments currently operating HACCP systems. Rather than select an arbitrary effectiveness estimate, or use the maximum potential 100 percent estimate from the preliminary analysis, this RIA will present a range of effectiveness estimates and show the minimum level necessary to generate net benefits.

6. Estimated Reduction in Cost of Foodborne Illness

Several comments focused on the issue that the relationship between pathogen reductions at the manufacturing stage and foodborne illness reductions is unknown. The comments recognize that the proposal did acknowledge that little data exist on the relationship between pathogen levels and incidence of illness. One comment pointed out that FSIS recognized that the pathogen testing requirements that are part of the proposal will help to elucidate the relationship between pathogen contamination and foodborne disease. The commenter concluded that it did not seem reasonable for the Agency to rely on an assumption, whose very validity can only be tested by the implementation of the proposal under examination, to justify the proposal.

Other commenters concluded that the Agency needed to develop better data or complete a thorough risk assessment that would establish the public health benefits of pathogen reduction before proceeding.

The comments asking for better data or requesting a thorough risk assessment are not comments on the cost-benefits analysis. These comments imply there is insufficient evidence to support new pathogen reduction efforts. This issue is addressed in the preamble to the final rule. The comments have made a policy judgment with which the Department does not agree.

For the benefits analysis included with the proposed rule, FSIS assumed that a reduction in pathogens will lead to a corresponding proportional reduction in foodborne illness. The Department notes that the IFSE study referred to favorably by many commenters used the same method for estimating public health benefits as did FSIS, i.e., a reduction in pathogens leads to a proportionate reduction in illness and death. The Agency is aware that the proportionate reduction method is an assumption that has not been tested or validated. However, the Agency also recognizes that research methodology for relating pathogen levels at establishments to incidence of illness is in its early developmental stages. Risk models for foodborne pathogens are likely to develop as the basis for regulatory decision-making in the future. The Agency believes the implementation of mandatory HACCP will improve food safety and protect public health while research in modeling risk associated with foodborne pathogens continues.

The Agency has and continues to support any effort to improve the quality of data and methodology available for risk assessment of illness caused by foodborne biological agents. FSIS, FDA, CDC, and local public health departments are collaborating with state health departments and local investigators at five locations nationwide to identify more accurately the incidence of foodborne illness, especially illness caused by *Salmonella* and *E. coli* O157:H7.

G. Summary

The final rule addresses four pathogens that are estimated to cause from $1.1 to $4.1 billion in annual illness and death costs attributable to meat and poultry products. The rule addresses 90 percent of that cost of illness or from $0.99 to $3.69 billion annually. FSIS recognizes that the actual effectiveness of the final requirements in reducing pathogens is unknown, and presents a range of benefits based on reducing varying percentages of the $0.99 to $3.69 billion in annual cost of foodborne illness addressed by this rule.

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V. Cost Analysis

A. Introduction

The final HACCP rule includes several regulatory components all directed at improving process control in meat and poultry operations in order to reduce the risk of foodborne illness associated with meat and poultry products. The requirements of the final rule are organized around the following three sections:

- Requirements that all inspected establishments develop and implement sanitation Standard Operating Procedures (SOP's) within 6 months.
- Requirements that all inspected establishments develop and implement HACCP programs within the 18 to 42 month time period following publication. Scheduling will be based on establishment size.
- Requirements that (1) all establishments slaughtering cattle, swine, chickens, or turkeys, or producing a raw ground product from beef, pork, chicken or turkey comply with new pathogen reduction performance standards for *Salmonella* and (2) all establishments slaughtering cattle, swine, chicken or turkeys implement microbial testing programs using generic *E. coli* within 6 months. Compliance with the pathogen reduction performance standards for *Salmonella* will be required at the time the establishment is required to implement HACCP.

This cost analysis is presented in three sections. The first section describes the methodology used in generating cost estimates. The next section addresses the regulatory flexibility designed to reduce the burden on small business. The last section presents the cost estimates for each regulatory requirement. For each broad requirement, the discussion of the cost estimates is organized using the following five topics:

- Summary of the requirements in the final rule identifying any changes from the proposal.
- Review of the cost estimates from the preliminary RIA.
- Summary of the comments related to the preliminary cost estimates.
- Response to the comments.
- Final cost estimates.

B. Methodology for Cost Analysis

The final pathogen reduction/HACCP rule includes regulatory requirements that are directed at improving the control over food processing operations. In general, compliance with these requirements requires expenditures of time, i.e., employee hours to develop plans, monitor critical control points, record findings and collect and analyze samples. This final RIA is based on time required by four categories of employees that were defined in the supplemental cost analysis. These include the following:

- Quality Control manager earning $25.60 per hour.
- Supervisors or QC technicians that review findings and records at $18.13 per hour.

• Laboratory technicians earning $18.13 per hour.

• Establishment employees/ production workers that would monitor sanitation and HACCP programs or collect samples at $12.87 per hour.

The four categories of wages are based on 1993 data adjusted for 1994 dollar inflation from the Bureau of Labor Statistics and *Meat and Poultry Magazine* and include a 33 percent overhead requirement for benefits such as health insurance and retirement contributions. Unless otherwise noted, the analysis assumes that all establishments and employees work a standard 52 week, 260 day, 2080 hour work year.

This final cost discussion is based on retracing the steps and/or calculations of the preliminary analysis and discussing related public comments in the appropriate sections. Other comments that are related to the analysis but do not reflect directly on the methodology are summarized at the end of the analysis in Appendix A.

This analysis makes frequent references to the Enhanced Economic Database. In 1994, the Research Triangle Institute (RTI) took a compilation of existing FSIS databases containing establishment production or inspection data and added data on annual sales and employment from sources that included Dun and Bradstreet and American Business List databases. Actual estimates for annual sales and number of employees were available for approximately 80 percent of the establishments. In other cases, estimates for sales and number of employees were developed using the employment/sales data for establishments producing the same type and volume of product.

The enhanced database includes production data (number of head slaughtered, pounds of product produced) from 1993 for all federally-inspected establishments in operation as of August 1994. The preliminary analysis and this final RIA combine 1993 production data with the population of federally and state-inspected establishments that were in operation as of August 1994. As of August 1994, there were 6,186 federally inspected and 2,893 state inspected establishments. These 9,079 establishments include a total of 11,719 ''operations''—2,597 red meat slaughter operations, 364 poultry slaughter operations and 8,758 further processing operations.

This final analysis assumes a constant level of 9,079 inspected establishments. The analysis does not attempt to account for costs associated with exits from or entries into the marketplace. For operations that are entirely new, or include a new processing operation, the requirements for HACCP plans and sanitation SOPs will increase the one-time, up-front cost of entering the market. If marketplace entry involves the purchase of an existing business, the business will already have an existing HACCP plan and sanitation SOP. In these cases, the acquisition cost of the business would include the value of the existing HACCP plan and SOP.

There should be minimal additional cost for HACCP and SOP plan development for new construction that expands a firm by replicating an existing operation in a new location. This type of new establishment can apply HACCP and SOP plans that have been developed for a similar existing establishment. This analysis has assumed that each establishment is independent and has not reduced cost estimates to account for firms that operate several similar establishments.

The preliminary analysis developed cost estimates for three sizes of manufacturing establishments. Most of the costs that involve employee time are influenced by a number of factors including the physical size of the establishment, the volume of production, the type of production practices and the number or production lines. The preliminary analysis used the data on annual sales developed by RTI because the sales data correlated reasonably well with size and production volume data and the Agency had an estimate of sales for 6,186 federally inspected establishments.

For the preliminary analysis the Agency defined a large establishment as one with over $50 million in annual sales, a medium establishment as one with between $2.5 and $50 million and a small establishment as one with less than $2.5 million in annual sales. For calculating costs, the Agency collected data from the field based on these three size categories. Public comments provided good reason to change size definitions for implementation (regulatory flexibility) purposes and the Agency has done so for the final rule. This does not affect the accuracy of proposed or current cost estimates based on previously collected data. The final analysis uses the old categories for presenting cost data to facilitate comparisons and minimize confusion. To summarize, this cost analysis uses the terms high, medium and low volume producers for cost presentation that involves average establishment costs and uses the terms large, small and very small business for discussing regulatory flexibility. The cost and flexibility principles do not overlap in this analysis.

Commenters pointed out that in comparing total costs with the value of current production, the preliminary analysis did not address impacts on producers, i.e., the costs that would be passed back to livestock producers. FSIS recognizes that some costs will be passed back to producers in terms of lower prices for live animals and other costs will be passed forward in terms of higher consumer prices. Other costs may have to be absorbed by slaughter and processing establishments. Because the necessary knowledge of empirical cost structures and supply and demand elasticities is inadequate, FSIS does not offer any quantitative estimates of the distribution of costs of this rule on various sectors of the production and marketing chain. The aggregate cost estimate establishes an upper bound on the costs any sector might ultimately bear.

There are two types of potential costs that were not addressed in the preliminary cost analysis. The first type of cost is the cost of taking corrective action when routine monitoring of a CCP finds a deviation from a critical limit. The critical limit could be associated with assuring compliance with existing regulatory requirements or it could be a limit set to assure compliance with the new pathogen reduction standards for *Salmonella* or the criteria established for generic *E. coli*. Corrective action would also occur when FSIS would find a problem with either a HACCP plan or a sanitation SOP.

The second type of potential cost is related to the question of whether existing processing methods are adequate to meet the pathogen reduction performance standards for *Salmonella* and the criteria for generic *E. coli*. It is expected that some establishments will have to make permanent changes to their existing production practices to have a HACCP-based program that assures compliance with the new standards and criteria. The final rule raises a third type of potential cost when it outlines the Agency's plans for using the results of its own *Salmonella* testing program for regulatory purposes. Whether or not this testing leads to industry testing costs depends on whether the government testing indirectly forces an establishment to regularly conduct its own testing.

The preliminary analysis did address a fourth category of potential costs that includes the cost of necessary materials, such as thermometers and test kits, that establishments will need to

systematically monitor their processes. Recognizing that the rule does not make any equipment obsolete, the preliminary analysis suggested costs of from $10 to $20 per establishment. These costs were not included in the overall cost summary.

Potential costs are addressed in this final analysis under Section V.D.2., Costs of Meeting Pathogen Reduction and Microbial Sampling Requirements.

C. Regulatory Flexibility

The Regulatory Flexibility Act (P.L. 96–354) requires analyzing options for regulatory relief for small businesses. This section reviews the regulatory relief provided in the proposal, responds to comments related to the definition of small business used in the proposal and summarizes the regulatory relief for small business provided for in the final rule. In Section II, this analysis addressed the option of providing an exemption for small business noting that comments on an exemption were mixed with a substantial number of comments from small businesses strongly opposing an exemption.

The proposed rule intended to spread the implementation of HACCP over a three year period. To minimize the burden on small establishments, they would be given a maximum time of 36 months to develop and implement their HACCP plans. A small establishment was defined as one with annual sales of less than $2.5 million.

The decision to use the above definition generated a large number of comments. ''Very small'' establishments commented that they could not compete with a relatively ''large'' business with annual sales of $2.5 million. For example one commenter stated that: ''calling an establishment, small, that produces $2,500,000 worth of product annually is not fair to those establishments producing far less.'' Other comments suggested that by defining small at the $2.5 million level, the Agency demonstrated that it does not understand what a small business is. Comments from businesses with annual sales of $2.5 to $10.0 million or even $25.0 million stated that they should also be considered small businesses. Commenters also pointed out that other Federal agencies use different definitions. For example, one commenter noted that OSHA uses 50 employees as their criterion for a ''small business.'' Others commented that FSIS should or must use the existing definition of fewer than 500 employees published by the Small Business Administration (SBA).

Several comments promoted a set of requirements distinguishing ''small'' from ''very small'' establishments. ''Very small'' establishments would only be required to implement the proposed provisions on sanitation standard operating procedures, antimicrobial treatment of carcasses, and time and temperature provisions. They would be exempt from routine microbial testing and long-term provisions of HACCP as long as annual sales do not exceed $1 million (not counting ''pass through''). The establishments would still be subject to incidental sampling for microbial testing as determined by the Administrator. Required implementation of the three near-term initiatives would be 12 months after publication of the final rule.

The ''small'' establishments (between $1.0 and $2.5 million) would be required to implement SOPs, antimicrobial treatment, time and temperature provisions, and limited routine sampling, in proportion to the number of slaughtered animals and/or poundage of processed products. The establishments would still be subject to incidental sampling for microbial testing as determined by the Administrator. They would be exempt from long-term provisions of HACCP as long as annual sales, as defined above, do not exceed $2.5 million. The required implementation of all near-term initiatives would be six months.

There were other comments that suggested variations on the above definitions and requirements for ''small'' and ''very small'' establishments. For example, one State department of agriculture recommended the same requirements for ''small'' and ''very small'' establishments but suggested that size criteria based on head slaughtered or pounds produced would be more practical. Another State department of agriculture recommended that a ''every small'' plant be defined based on the number of employees (no more than 20 full-time), slaughter volume (no more than 2,500 animals per year), or processing volume (100,000 pounds of meat and/or poultry products per year). The recommendation suggested that a plant in this category would be required to implement the provisions of the proposed rule pertaining to sanitation SOP's and time-temperature requirements. Antimicrobial treatment of carcasses would be voluntary, and such a plant would be exempted from microbial testing as proposed. Implementation of a HACCP program would be initially voluntary, and phased in with considerations in the areas of documentation and record-keeping for the limited work force.

FSIS has considered the above regulatory framework for ''small'' and ''very small'' establishments. Some of the suggestions are no longer applicable because major provisions of the proposed rule have been dropped. FSIS believes it has addressed the other concerns in more appropriate ways.

FSIS was aware of SBA Size Standards during the development of the proposed rule. If FSIS used the size standard for meat and poultry ''manufacturing'' firms, over 94 percent of the federally inspected establishments would meet the criterion of having fewer than 500 employees. FSIS is also aware that there are six different SBA size standards that apply to the 6,415 FSIS official establishments. FSIS determined the SBA size standards by themselves are not appropriate for meeting FSIS's need to sequence HACCP implementation.

Table 7 shows the distribution of 6,415 official establishments by Standard Industrial Classification (SIC) code. The SIC codes were developed to promote the comparability of statistics describing various facets of the Nation's economy. The SIC codes were used as part of the Enhanced Economic Analysis Database developed by Research Triangle Institute to represent all FSIS inspected establishments. As can be seen from Table 7, a significant portion of official establishments are not in an SIC Code for manufacturing. Food manufacturing establishments have a 4-digit SIC Code beginning with 20. The Census of Manufacturers published by the Department of Commerce characterizes the meat and poultry manufacturing industry by summarizing data for SIC Code 2011—Meat Packing Establishments, SIC Code 2013—Sausages and Other Prepared Meats, and SIC Code 2015—Poultry Slaughtering and Processing. The SBA Size Standards in Table 7 are published in the Code of Federal Regulations—13 CFR, Chapter 1, Section 121.601.

In a written comment, the Office of Advocacy, Small Business Administration claimed that FSIS was wrong in concluding that one-third of federally inspected establishments would have the maximum time for compliance with HACCP requirements using the criterion of $2.5 million in annual sales. In supporting their claim, they cited U.S. Census Bureau data. However, Census data do not accurately describe the federally inspected meat and poultry industry. As shown in Table 7, the problem is that less than half of the firms are classified in the three 4-digit SIC Codes identified above that define meat and poultry manufacturing. FSIS addressed this data

problem by contracting with RTI to develop a more accurate economic profile of federally inspected meat and poultry establishments.

TABLE 7.—ESTABLISHMENTS STANDARD INDUSTRIAL CLASSIFICATION

SIC code	Standard industrial classification	Number of establishments	Cumulative number of establishments	SBA size standard
2011 ...	Meat packing establishments	1,503	1,503	500 employees.
5147 ...	Meats and meat products	1,312	2,815	100 employees.
2013 ...	Sausages and other prepared meats	939	3,754	500 employees.
2015 ...	Poultry slaughtering and processing	438	4,192	500 employees.
4222 ...	Refrigerated warehousing and storage	356	4,548	$18,500,000.
5421 ...	Meat and fish markets	309	4,857	$5,000,000.
5144 ...	Poultry and poultry products	268	5,125	100 employees.
5141 ...	Groceries, general line	238	5,363	100 employees.
5812 ...	Eating places	156	5,519	$5,000,000.
2038 ...	Frozen specialities, nec	139	5,658	500 employees.
5142 ...	Packaged frozen foods	130	5,788	100 employees.
5411 ...	Grocery stores	95	5,883	$20,000,000.
5149 ...	Groceries and related products, nec	65	5,948	100 employees.
9999 ...	Not applicable	63	6,011	
2032 ...	Canned specialities	61	6,072	1,000 employees.
2099 ...	Food preparations, nec	55	6,127	500 employees.
Other	All other SIC codes	288	6,415	

Note: The Enhanced Economic Analysis Database uses the number of active establishments as of August, 1994 and identified 6,415 establishments as active official establishments. Of these 6,415, a total of 229 were identified as cold storage/ID warehouses, universities or churches. From the 6,415 total, 6,186 federal establishments were classified as processing, slaughter or combination operations. nec—(Not Elsewhere Classified).

The final rule provides for sequencing HACCP implementation by establishment size, using the SBA definition of a small manufacturing business, i.e., a small business is an establishment with fewer than 500 employees. Those establishments with 500 or more employees will be referred to as large establishments. In addition, in response to comments that there are hundreds of ''very small'' or ''micro'' establishments, the Agency will classify an establishment as ''very small'' if it has either fewer than 10 employees or annual sales of less than $2.5 million.

This sequencing of HACCP responds to a large number of comments requesting that small businesses be given a longer period of time to implement HACCP requirements. Many small businesses stated they did not want to be exempt, but asked for more flexibility in implementing HACCP. Some commenters specifically requested five, eight or 10 years to implement HACCP.

While the final rule does not provide for longer periods of five, eight or 10 years, it does substantially extend the implementation period for hundreds of small and very small establishments.

To illustrate, the proposed rule would have required HACCP plans in over 2,100 establishments producing raw ground product within 12 months. Under the final rule, over 1,800 of those establishments will have either 30 or 42 months to implement HACCP. The smallest 5,127 establishments (2,893 state and 2,234 federal) will have an additional six months. The proposed rule called for implementation of a HACCP system in all ''small'' establishments by 36 months; the final rule allows 42 months for the newly defined ''very small'' category.

Table 8 illustrates the distribution of 6,186 federally-inspected slaughter, processing, and combination establishments used for the sequencing of HACCP implementation in the proposed rule and in the final rule. There are 496 more establishments in the two smaller categories than there were in the proposal. As shown in Table 8, there are 353 large, 2,941 small and 2,892 very small federally-inspected establishments.

TABLE 8.—SIZE CATEGORIES FOR FEDERALLY INSPECTED ESTABLISHMENTS

Establishment category	Definition	No. of establishments
Proposed Rule		
High volume	>$50 million	849
Medium volume	$2.5–$50 million.	3,103
Low volume	<$2.5 million.	2,234
Total		6,186

TABLE 8.—SIZE CATEGORIES FOR FEDERALLY INSPECTED ESTABLISHMENTS—Continued

Establishment category	Definition	No. of establishments
Final Rule (Sequencing of HACCP)		
Large	≥500 Employees.	353
Small[a]	10–499 Employees.	2,941
Very small[b]	<10 Employees or <$2.5 Million.	2,892
Total		6,186

[a] New definition of small includes 2,445 establishments that were medium volume establishments plus 496 that were high volume for the preliminary analysis.

[b] New definition of very small includes the 2,234 establishments that were low volume establishments plus 658 that were medium volume establishments for the preliminary analysis.

D. Final Cost Estimates

1. Sanitation Standard Operating Procedures

a. Summary of Requirements. The final rule requires that all inspected establishments develop and implement Sanitation SOP's within 6 months after publication of the final rule. The proposed rule would have required the implementation of SOP's within 90

days. To facilitate the development of SOP's and to provide maximum flexibility, the Agency will not prescribe any specific format or content but will provide guidelines to assist inspected establishments in developing written SOP's. There will not be any FSIS approval of the written documents. With the exception of the implementation schedule, the requirements for SOP's in the final rule are the same as those in the proposed rule.

b. Review of Preliminary Cost Estimates. The preliminary cost analysis identified separate costs for SOP plan development and SOP recordkeeping where recordkeeping was defined as observing or verifying procedures, recording findings, reviewing records and maintaining files. FSIS assumed that the Sanitation SOP's would be developed by a quality control manager at a cost of $25.60 per hour. FSIS estimated that it would cost an average of $128, $256 and $640 for low, medium and high volume establishments to develop Sanitation SOP's.

The preliminary cost analysis assumed that Sanitation SOP's observation and recording for low, medium and high volume establishments would take 15, 25 and 45 minutes per day by an employee earning $12.87 per hour and that supervisory review of records would take 5, 10, and 20 minutes by an employee earning $18.13 per hour. In developing these time estimates for recording and reviewing records, FSIS recognized that the time required would be influenced by a number of factors including the physical size of the establishment, the volume of production, the type of production practices and the number of production lines. The estimates are based on program judgement of the time required to conduct two sets of sanitation observations per day, one for preoperational sanitation procedures and one for operational sanitation.

Using the above inputs, the annual costs for recording and reviewing Sanitation SOP's records for low, medium and high volume establishments would be approximately $1,230, $2,180 and $4,080, respectively, based on a 260-day, 2,080 hour work year. These costs were adjusted upward to approximately $1,242, $2,204 and $4,104 to account for the cost of maintaining records.

The preliminary analysis also included training costs of $62, $155 and $372 for low, medium and high volume establishments. Instructing an employee in verification and recording procedures was assumed to take 2, 5 and 12 hours, respectively involving both a QC technician ($18.13 per hour) and a production worker ($12.87 per hour). Total training cost was, therefore, $31 per hour. Total per establishment Sanitation SOP's costs, as estimated in the preliminary analysis, are summarized in Table 9.

TABLE 9.—SUMMARY OF SANITATION SOP COSTS PER ESTABLISHMENT

[Dollars]

Establishment category	Plan development cost	Annual recordkeeping cost	Training cost	Total first year cost	Recurring annual cost
Low	128	1,242	62	1,432	1,242
Medium	256	2,204	155	2,615	2,204
High	640	4,104	372	5,116	4,104

Using the per establishment costs from Table 9, total aggregate costs were calculated for all inspected establishments as shown in Table 10. Establishments with an existing written sanitation program were assumed to have only 50 percent of the plan development costs because these establishments would have to modify an existing plan rather than start from the beginning. Establishments with existing sanitation plans include the 287 establishments with TQC programs and 46 slaughter establishments with PQC sanitation programs. It was also assumed that these 333 establishments would not require training to implement a sanitation SOP.

TABLE 10.—COSTS OF SANITATION SOP'S

[Dollars in thousands]

Establishment category	No. of establishments	First year costs	Recurring costs
High	849	$4,276	$3,484
Medium	3,103	8,079	6,839
Low	2,234	3,185	2,775
Subtotal	6,186	15,540	13,098
State	2,893	4,143	3,593
Total	9,079	19,683	16,691

Note: For preliminary RIA, all State establishments were assumed to be low volume establishments.

c. Comments on Preliminary RIA. Comments on proposed requirements for sanitation Standard Operating Procedures (Sanitation SOP's) focused on the cost of recordkeeping. In the preliminary cost analysis, recordkeeping included observation (i.e., verifying the procedures), recording findings, supervisory review of records and maintenance of files. One commenter stated that the cost of recordkeeping for their company would be approximately $10,000 annually.

A state inspected establishment, currently participating as a pilot establishment for HACCP/sanitation plans in their state program, indicated that they spend several hours each week verifying procedures and have weekly costs of at least $50 to keep the paperwork for their sanitation plan current. Their annual cost for keeping paperwork current would, therefore, be at least $2,600. This state establishment also stated that they had used an estimated $3,000 to $4,000 designing an SOP and that was with the assistance of two universities, several suppliers and their state inspection program. It took nine months to put the plan together.

Comments at public hearings indicate that there is a lot of uncertainty as to what FSIS expects in Sanitation SOP's. At one of the public hearings the owner of a ''small'' establishment stressed the importance of guidance and training with respect to what is expected in terms of recordkeeping.

d. Response to Comments.

The Agency recognizes that the costs reported by the state establishment participating in a pilot program are substantially higher than the costs used in the preliminary analysis. The reported development time of nine months is also longer than the allowed implementation period. FSIS believes that the reported pilot project involving two universities, several suppliers and a state program has far exceeded the expectations of the rule. The same is true for the comment suggesting recordkeeping costs of $10,000 per year.

FSIS has now developed model Sanitation SOP's and a guideline for developing Sanitation SOP's. These documents should clarify FSIS expectations. FSIS believes that these documents are consistent with the cost estimates used in the preliminary analysis.

There is some reason to believe that the estimated cost for Sanitation SOP's in the preliminary analysis is conservative, that is, a possible overstatement of costs. Whether the costs associated with Sanitation SOP's are totally new or just how they may be modified over time can only be determined in individual establishment situations. For example, task verification and recordkeeping are costs that can be reduced through efficient management and allocation of resources and should decrease with experience. In many cases the tasks can be integrated with current duties.

For many establishments, the cost of Sanitation SOP's should be offset by changes in the approach to sanitation. Under current procedures, slaughter operations can not begin until inspection personnel have given their approval. Under the new procedures all establishments will be able to commence daily operations without USDA approval upon successful completion of the preoperational portion of their Sanitation SOP. When operational sanitation problems are identified, corrected and documented as they occur by the establishment, establishment officials will spend less time interacting with inspectors or responding to inspection findings. For example, federally inspected establishments currently provide written responses to approximately 700,000 to 800,000 Processing Deficiency Records (PDRs) per year. Over 70 percent of these PDRs are for sanitation deficiencies.

Finally, while FSIS recognizes that keeping sanitation records will be a new task, FSIS does not necessarily view the time spent verifying sanitation procedures as a new regulatory cost. FSIS is not changing any sanitation requirements. It is also true that FSIS has had an ongoing problem getting all establishments to comply with existing sanitation requirements. It can, therefore, be argued that some establishments have not conducted the necessary verification to assure compliance with existing regulations or have used FSIS employees to conduct sanitation verification.

e. Final Cost Estimates. After considering the comments, FSIS does not see a need to adjust the cost estimates shown in Tables 9 and 10. The final aggregate cost estimates for SOP's are those shown in Table 10. The costs in Table 10 assume that the requirement for SOP's does not lead to new compliance costs associated with new regulatory obligations apart from paperwork and recordkeeping. The analysis assumes that satisfactory sanitation is achieved one way or another under current procedures and that the changes that will occur with SOP's have more to do with issues of responsibility and efficient use of inspection resources. It follows that, for the most part, this provision of the rule will have no direct effect on the rate, extent or severity of pathogenic contamination, and thus will also have no effect on the rate, extent, or severity of foodborne illness. This is not saying there will be no change in establishment or employee conduct. In fact, FSIS expects to see more sanitation activities conducted at the firm's initiative rather than following inspection findings.

2. Costs of Meeting Pathogen Reduction and Microbial Sampling Requirements

a. Summary of Requirements. The final rule implementing HACCP-based programs establishes pathogen reduction performance standards for *Salmonella.* The rule both establishes the standards and defines the procedures the Agency will use to measure and assure compliance with the standards. The rule does not specify a minimum testing requirement for *Salmonella.* The pathogen reduction performance standards apply to an estimated 5,522 inspected establishments, 2,682 establishments that slaughter cattle, hogs, chicken or turkeys and another 2,840 establishments that do not slaughter, but produce raw ground product from beef, pork, chicken or turkey. If an establishment slaughters two species, e.g. cattle and hogs, the establishment would be subject to the standards for both cattle and hogs. The Agency's testing program would, however, be directed at the predominant species. If an establishment both slaughters and processes a raw ground product from that same species, the Agency will test the ground product. If an establishment produces more than one variety of ground product, the Agency intends to sample each.

The proposed rule included the same standards but contained a different approach for enforcement. The proposed rule included the requirement that each of the 5,522 affected establishments would collect and analyze one sample for each species or variety of raw ground product for *Salmonella* on a daily basis. The establishments would maintain records from these tests that would be reviewed by inspection program personnel to determine compliance. The proposed rule did not include a discussion of how the Agency would use the test results in a program for regulatory enforcement.

Under the proposal, the results from each establishment's *Salmonella* testing program were also to be used as a measure of process control. This final rule requires that all 2,682 slaughter establishments implement sampling programs using generic *E. coli* as a measure of process control for slaughter and sanitary dressing procedures.

b. Review of Preliminary Cost Estimates. As discussed earlier under methodology, the preliminary RIA did not attempt to analyze the overall impact of complying with the new pathogen reduction standards. The preliminary RIA did include a detailed analysis of the costs associated with the requirement that slaughter and raw ground processing establishments collect and analyze samples for *Salmonella* on a daily basis. The laboratory analysis required only a positive-negative finding, i.e., the proposed rule did not require the analysis necessary to determine the number of bacteria present in the sample. The cost of meeting the proposed requirement would vary depending on whether or not the establishment had an inhouse laboratory. It was assumed that approximately 20 percent of samples would be collected in establishments with in-house laboratories. For an establishment without a laboratory the total cost for each sample was estimated as shown in Table 11.

TABLE 11.—COST OF A SALMONELLA SAMPLE ANALYSIS FOR ESTABLISHMENTS WITH NO IN-HOUSE LABORATORY

(Dollars)

Component	Cost
Average Private Laboratory Cost	22.60
Shipping	7.00

TABLE 11.—COST OF A SALMONELLA SAMPLE ANALYSIS FOR ESTABLISHMENTS WITH NO IN-HOUSE LABORATORY—Continued

(Dollars)

Component	Cost
Collecting and Packaging	3.75
Total	33.35

The establishment without an in-house laboratory would also be required to train an individual to perform aseptic sampling. The cost components for a *Salmonella* test at an in-house laboratory were estimated for the preliminary RIA as shown in Table 12.

TABLE 12.—COST OF A SALMONELLA SAMPLE ANALYSIS FOR ESTABLISHMENTS WITH AN IN-HOUSE LABORATORY

[Dollars]

Component	Cost
Laboratory Supplies	5.90
Collecting and Preparing Sample	5.28
Laboratory Analysis (0.5 hours at $18.13 per hour)	9.07
Total	20.25

Since the requirements in the final rule have changed substantially, this section will present only a brief summary of what was a relatively complex analysis to estimate the total industry sampling costs associated with the proposed requirements. The costs associated with the proposed *Salmonella* testing requirement are summarized in Tables 13 and 14. Table 13 shows the different cost components.

TABLE 13.—COMPONENT COSTS FOR MICROBIAL SAMPLING AS PROPOSED

[$ Thousands]

Establishment category	Training for aseptic sampling	Sampling plan development	Sample collection and analysis	Recording and review time
High	10	508	5,267	242
Medium	514	1,473	20,555	887
Low	604	959	18,624	606
Subtotal	1,128	2,939	44,446	1,735
State	998	1,588	21,150	688
Total	2,126	4,527	65,597	2,423

TABLE 14.—AGGREGATE COSTS OF MICROBIAL SAMPLING AS PROPOSED

[$ Thousands]

Establishment category	Number of raw product operations	First year costs	Recurring costs
High	793	6,027	5,509
Medium	2,301	23,429	21,443
Low	1,498	20,792	19,230
Subtotal	4,592	50,248	46,181
State	2,481	24,424	21,838
Total	7,073	74,672	68,020

Note: All state establishments were assumed to be low volume producers. Columns may not add to totals due to rounding.

Table 14 summarizes the first year and annual recurring costs. Training and sampling plan development costs are one-time first year costs. Sample analysis and recording costs are both recurring annual costs. The following notations help characterize the estimated costs from the preliminary analysis:

- Training and plan development costs were based on a total of 7,073 raw product operations. This total is based on a count of meat slaughter, poultry slaughter and raw ground processing operations. Sample collection and analysis and recording and record review costs were based on a count of 8,329 species-specific operations, i.e., the total of beef slaughter, pork slaughter, raw ground processing, etc. Thus, an establishment with beef slaughter, pork slaughter and raw ground processing would count as two operations for training and plan development, but three operations for sampling and recordkeeping.
- The proposed requirement of one sample per day per species resulted in low volume federal establishments and state establishments accounting for over 60 percent of the estimated first year costs (See Table 14).
- The analysis underestimated costs in that with existing data it was necessary to assume that the 3,029 establishments with raw ground product operations produced only one product. The proposal would have required 2 samples per day if an establishment produced both raw ground beef and raw ground pork on a daily basis.
- The analysis overestimated costs in that it counted operations for minor species or kind (e.g. sheep and goats). The proposal did not cover sheep, goats, equine, ducks, geese, etc.
- The analysis overestimated costs in that it assumed that every establishment

with multiple operations was running each operation every day (260 days per year).

• Each of the 7,073 operations would require a sampling plan—25 hours for a QC manager at $25.60 per hour for a total of $640 per plan. At $640 per plan, 7,073 plans totaled $4.53 million as shown in Table 13.

• The analysis assumed that 5,275 (approximately 75 percent) of the 7,073 operations would have to train an individual to perform aseptic sampling. The total of 5,275 includes all 1,498 low volume raw operations, 1,275 (55.4%) of the 2,301 medium volume raw operations, 25 (3.2%) of the 793 high volume operations and 2,477 (99.8%) of the State inspected raw product operations. Training was estimated at $403 per operation—8 hours with a trainer at $37.50 per hour and a trainee at $12.87 per hour. Training for 5,275 operations at $403 per operation would cost $2.13 million as shown in Table 13.

• Recording and review time was estimated at 5 minutes per day for each of the 8,329 species-specific operations. Five minutes per day equals approximately 21.7 hours per year or an average of approximately $291 per year per operation based on wages of $18.13 and $12.87 per year (average of $13.43). The total is $2.42 million as shown in Table 13. Since the requirement was one sample per day per species, the cost estimates could also be viewed as 5 minutes per sample.

c. Comments on the Preliminary RIA. Similar to the preliminary analysis, the public comments focused on the cost of required *Salmonella* sampling and did not address the overall impact of meeting the proposed pathogen reduction performance standards for *Salmonella.* The proposed regulation would have required daily sampling for each species or kind slaughtered and each type (meat or poultry) of raw ground product per establishment per day. Comments from individual establishments indicated that some small establishments could be required to take 5 or more samples per day. A ''small'' establishment currently slaughtering three different species (beef, swine and lamb) and producing multiple raw ground products estimated they would need approximately 2,200 samples per year at a cost of approximately $77,000 per year. That is over eight per day based on a 260 day work year. A ''small'' ground meat processing establishment estimated they would need over 500 samples from approximately 350,000 pounds of annual production.

Several comments from ''small'' establishments pointed out that the proposed sampling program placed a disproportionate burden on small establishments from two perspectives. First, ''small'' establishments have less production over which to spread the cost of sampling. Second, smaller establishments tend to be the ones that slaughter more species or kind and produce more varieties of raw ground product. Other comments pointed out that the proposed *Salmonella* testing would not provide a good procedure to validate process control.

There were also comments that referred to the cost of the product that is lost or damaged during sample collection. A turkey processor noted that the value of a 40 pound tom is $63.60 at wholesale price. The same comment pointed out that shipping costs could be very high, especially if next day service is required.

Several comments noted that the IFSE study estimated costs for microbiological testing that were far higher than the cost estimates provided by FSIS. Another commenter noted that microbiological testing is being proposed to correct a deficiency of an inspection system that is currently unable to detect microbial contamination of meat. If mandatory inspection is a federally funded program, why not the ''correction'' of the system?

Most of the comments referred to the cost of the proposed requirement and were not comments on the methodology used to determine costs in the preliminary analysis. One comment that did address the cost methodology had calculated the cost of a *Salmonella* test at $38.00 to $44.50 per test where FSIS used a cost of approximately $33.00 to $34.00. There was some confusion concerning the proposed requirements. Some comments indicated the establishments believed that they would have to test every product line. Other comments based estimates on a far costlier test for *Salmonella* indicating they assumed the test would require information concerning the number of bacteria present, not just a positive-negative result.

There were also comments that suggested that FSIS has overestimated the cost of microbial sampling because, as the amount of laboratory analysis increases, the cost per sample will probably decrease. Other commenters pointed out that demand will lead to simpler and less costly new methods development.

d. Response to Comments. The changes in the final rule eliminate the issues raised by most of the comments. The comments concerning the burden on ''small'' establishments made a convincing argument that ''small'' establishments could not afford to implement the microbial sampling program as proposed. The final rule does not include a minimum testing requirement for *Salmonella.* Each individual establishment can conduct the level of testing they deem necessary to provide assurance that they are meeting the pathogen reduction performance standards for *Salmonella.*

The Agency agrees with public comments and conclusions reached at technical conferences that the proposed *Salmonella* testing would not have provided a good measure of process control. The final rule requires that all slaughter establishments implement testing programs using generic *E. coli* to validate control of slaughter and sanitary dressing procedures. After reviewing all public comments and other materials made available during the comment period, FSIS concluded that using generic *E. coli* is more practical. Generic *E. coli* is generally present in the feces of mammals and birds and is, therefore, an excellent indicator of fecal contamination. It has a higher frequency than *Salmonella* and can be tested and quantified relatively less expensively and, therefore, provides a more efficient measure of control of slaughter and sanitary dressing procedures. Testing for generic *E. coli* is also easier for in-house establishment laboratories.

By basing *E. coli* sampling programs on production volume, the Agency is responding to small establishment concerns over equity of the regulatory burden. In addition, establishments with very low production will be required to conduct sampling for only a limited time period each year. Sampling will only be required for slaughter establishments. Establishments slaughtering more than one kind of poultry or species of livestock will be required to sample only the kind or species representing the most production. There will also be provisions for decreasing the number of samples after implementation of HACCP plans and provisions for using alternative generic *E. coli* sampling programs in cases where the establishment can present data demonstrating control of slaughter and sanitary dressing procedures.

The comments referring to the value of lost product identified a cost that was not addressed in the preliminary analysis. Such costs will not be a factor for the final rule because beef and pork samples collected by FSIS will use the wet sponge swab technique and poultry samples will be collected using a whole

bird rinse. In both cases, no product will be damaged or lost.

With respect to comments referring to high microbial sampling costs identified by the IFSE study, FSIS notes that the Agency's preliminary cost estimates were based on the proposed regulatory requirement of one test per species (carcass or raw ground product) per day for *Salmonella.* The IFSE study based their per establishment costs on a microbiological testing program currently being used in a beef slaughter establishment. The cost estimates generated by the IFSE study were not related to the testing program outlined in the proposed rule.

The comments were correct that FSIS based the preliminary cost analysis on existing laboratory methods and on current laboratory cost estimates. The comments suggesting less expensive methods are only speculative. There is no way to estimate potential new methods. While there is no way to predict the effect of increased demand on costs, it seems reasonable to expect that, in the long run, laboratory analysis costs per sample will go down as more firms implement microbial sampling programs. FSIS notes that short run costs could actually increase as demand goes up faster than the supply of laboratory capability. In the long run, however, establishments should benefit from quantity discounts and lower fixed costs per sample as the total number of analyses increases.

e. Final Cost Estimates. The final rule requires that all establishments slaughtering cattle, hogs, chickens or turkeys or producing a raw ground product from these species or kind meet a new pathogen reduction performance standard for *Salmonella.* This requirement applies to an estimated 5,522 establishments as shown in Table 15. Because the standard has been established using the baseline studies that estimate a national prevalence by carcass, the Agency does not have an estimate for the number of establishments that are currently meeting the standard. The baseline studies do not provide data on how pathogen levels vary between establishments and include data from only the larger establishments that represent most of the production.

TABLE 15.—ESTABLISHMENTS AFFECTED BY THE PATHOGEN REDUCTION PERFORMANCE STANDARD

Category	Very small	Small	Large	Total
Cattle and hog slaughter	1,876	376	66	2,318
Poultry slaughter	100	121	143	364
Raw ground processing	1,413	1,358	69	2,840
Total	3,389	1,855	278	5,522

This analysis of how the *Salmonella* standards will impact the 5,522 establishments will, by necessity, be primarily a qualitative discussion. The analysis will, however, develop two scenarios that can be used to present a range of potential impacts.

Since the focus of this rule is about reducing pathogens in or on raw meat and poultry products, it is anticipated that the potential costs are greatest for those slaughter establishments that are currently not meeting the new pathogen reduction performance standards. For slaughter establishments, the potential costs take one of two forms.

First, even though the rule does not require establishments to test for *Salmonella,* the Agency recognizes that some establishments may conduct their own *Salmonella* testing programs to avoid failing a series of tests conducted by the Agency. Thus, it can be argued that the Agency's intent to implement establishment specific testing for *Salmonella* is indirectly requiring the industry to routinely monitor their *Salmonella* levels to assure they will be in compliance.

The manner in which FSIS will implement its *Salmonella* testing program should help keep establishment costs down. During the first phase, referred to as pre-implementation testing, FSIS will test product from each slaughter or raw ground operation and share those results with the establishment. Thus, before FSIS begins the actual enforcement of the *Salmonella* performance standards, the Agency will provide each establishment with a status report on *Salmonella* incidence. This pre-implementation testing will precede HACCP implementation, which occurs from 18 to 42 months after publication of the final rule. The pre-implementation results will assist the establishments in preparing for implementation of HACCP and the pathogen reduction performance standards. Establishments with low incidence of *Salmonella* will have some level of assurance that they are already meeting the new *Salmonella* standards.

The second type of potential cost relates to the question of whether firms will have to make permanent changes in their processing or production practices in order to comply with the pathogen reduction performance standards for *Salmonella.* Reducing pathogens for slaughter establishments involves either modifying the incoming animals or birds, improving the dressing procedures so as to reduce contamination during procedures such as hide removal and evisceration, or using interventions such as antimicrobial treatments to kill or remove the pathogens following contamination. For many establishments, the process of implementing HACCP programs may, by itself, improve the dressing procedures sufficiently to meet the new standard. Other establishments may have to choose between slowing production lines, modifying some attribute of their incoming live animals or birds, or adding post-dressing interventions such as the new steam vacuum process or antimicrobial rinses.

This analysis will examine the two types of costs for the three industry segments of poultry slaughter, meat slaughter and raw ground processing. The analysis develops two cost scenarios to estimate the impact of the new pathogen reduction standards for *Salmonella.* As discussed earlier, the Agency does not have an estimate for the number of establishments that are currently meeting the standards.

The two cost scenarios are based on three general premises. The first premise is that a certain portion of large establishments will take whatever action is necessary to provide assurance that they are meeting all regulatory requirements. The second premise is that the establishments that are typically having problems controlling operations today will also have problems meeting the *Salmonella* standards. The low cost scenario is based on these first two premises. FSIS has historically found serious control problems in from 5 to 10

percent of establishments. The recent 1,000 establishment review found serious control problems in 8.9 percent of 358 randomly selected establishments. The 1993 review of establishments with the New Turkey Inspection System found 3 of 26 establishments with problems with product ready for shipment. A 1991–1992 survey of poultry reprocessing found that while only 2 percent of poultry is reprocessed off-line, from 5 to 10 percent of the establishments had very high reprocessing rates.

The high cost scenario is based on a third premise that (1) approximately half of the affected establishments are currently not meeting the standards and that (2) most large establishments and the majority of smaller establishments will take some action to assure compliance with the *Salmonella* standards.

As shown in Table 15, there are 2,318 cattle or swine slaughter establishments that must meet the pathogen reduction performance standards for *Salmonella*. The Agency does not have information that would indicate that *Salmonella* testing is routinely conducted by a major segment of the beef or pork industry. The baseline studies have shown a one percent positive rate for steers and heifers and a 2.7 percent positive rate for cows and bulls. In addition, the Agency does not know how, or if, beef and pork establishments would respond to the Agency's *Salmonella* testing initiative. Given the relatively low levels of *Salmonella*, most establishments will probably choose to depend on the assurance provided by a validated, well functioning HACCP program.

To develop a low cost scenario, the Agency assumes that the 66 large establishments would initiate daily testing using in-house laboratories ($20.25 per analysis—$347,490 per year) and that half of the 376 small establishments would conduct weekly testing at outside laboratories ($33.35 per analysis—$326,030 per year). Under a high cost scenario, the large establishments would conduct 8 tests per day ($2.78 million per year), the small establishments would all conduct one test per week ($652,059 per year) and half (938) of the very small establishments would conduct a test each month ($375,388 per year). The low and high *Salmonella* sampling costs for cattle and hog slaughter operations are summarized in Tables 16 and 17, respectively.

Beyond testing, there is the issue of whether the required actions of developing and implementing process control procedures will, by themselves, be sufficient to meet the *Salmonella* standards or whether changes in processing methods will also be required. FSIS recognizes that beef and pork dressing procedures involve a lot of manual steps and, therefore, it is reasonable to assume that substantial pathogen reduction can be accomplished through training and careful monitoring of the dressing procedures. This is especially true for the low volume establishments that do not have automated lines and use what is known as the ''bed kill'' dressing process.

For slaughter establishments that do have to make process modifications, there are several options available. First, FSIS is aware of establishments that are testing live animal washing systems. Second, the preliminary analysis included estimates for the cost of using different antimicrobial treatments for varying sizes of cattle or hog slaughter establishments. The lowest cost option was a hot water spray system with no cabinet. The cost for that system was estimated at $.08 per carcass or approximately $8.78 million annually for all cattle and hog establishments. In contrast, a pre-evisceration acid spray system with both a pre-wash spray cabinet and a sanitizing cabinet was estimated at $.79 per carcass for a low volume establishment. A TSP system for cattle was estimated at $.85 per carcass for a low volume establishment.

The preliminary analysis noted that 23 establishments were already using acetic or lactic acid sprays on carcasses either before or after evisceration. Other establishments had requested approval for citric acid, TSP, or hot water.

Third, FSIS has now approved the new steam vacuum systems for beef and pork operations. The installation of a steam vacuum system is estimated at $10,000 per establishment, with expectations that increased use will result in lower prices. Annual increased utility costs to run a steam vacuum system are estimated at $4,000. Maintenance cost is estimated at 5 percent or $500 per year.

For a low cost option, it is assumed that 10 percent of the large establishments must install a steam vacuum system to meet the new requirements and that half of 376 small establishments must use a hot water rinse at $.08 per carcass. The initial costs for the steam systems would be $70,000. Annual operating costs would be $31,500. Annual operating costs for hot water rinses on half the small establishment production would be $915,000.

Under a high cost option, it is assumed that half (33) of the large establishments would have to install steam systems and that all small and very small establishments would use hot water rinses. The initial cost for steam systems would be $330,000. Annual operating costs would be $148,500. Annual costs for hot water rinses would be $2,075,387. The low and high process modification costs for cattle and hog slaughter operations are summarized in Tables 16 and 17, respectively.

As shown in Table 15, there are an estimated 2,840 establishments that produce raw ground products using ingredients from other establishments. These establishments do not have the same opportunities to reduce *Salmonella* levels as do slaughter establishments. They can control growth by avoiding temperature abuse and can limit cross-contamination, but basically they must depend on the *Salmonella* levels of their incoming product in order to meet the performance standards. These establishments may choose to test incoming product in order to eliminate suppliers whose product is found to be positive. Larger establishments that are important customers of other suppliers may choose to include pathogen requirements in their purchase specifications.

For a low cost scenario, this analysis assumes that the 69 large firms would analyze one sample per day using in-house laboratories ($20.25 per analysis) and that 10 percent (136) of the small firms would test one sample per week using an outside laboratory ($33.35 per analysis). Under a high cost scenario, this analysis assumes that half (679) of the small firms would test one sample per week and that the large firms would double their sampling. Under each scenario, it is assumed that the large establishments would begin testing 12 months after publication and the small establishments 24 months after publication. These starting dates correspond with the end of the Agency's pre-implementation testing. The low and high *Salmonella* sampling costs for raw ground processors are summarized in Tables 16 and 17, respectively.

As shown in Table 15, there are 364 poultry slaughter operations that will be required to meet the new pathogen reduction performance standards for *Salmonella*. FSIS believes that almost all of the larger establishments in the poultry industry currently conduct routine or periodic analyses for *Salmonella* and will use their ongoing testing programs to (1) establish and validate their HACCP controls to assure they will initially comply with the new pathogen reduction performance

standard, and (2) periodically verify continuing compliance. Therefore, the costs for additional *Salmonella* testing in the poultry industry will be minimal.

For cattle and hog operations, this analysis used the cost of antimicrobials from the preliminary analysis in estimating possible process modification costs. In contrast, for the poultry industry, meeting the pathogen reduction performance standards is clearly not analogous to meeting the proposed antimicrobial requirement. The preliminary analysis assumed that 90 percent of all high volume poultry processors and 70 percent of all low or medium volume processors already meet that proposed requirement.

FSIS recognizes that many poultry establishments may have to modify existing procedures to meet the new standards for *Salmonella*. Where cattle and hog dressing operations still include many manual procedures that can be easily controlled by improved training and monitoring, the poultry slaughter industry is highly automated, increasing the probability that process control may require modifications of equipment, facilities, or incoming product. However, because there is extensive vertical integration in the poultry industry, many firms have the added option of controlling *Salmonella* in the live birds. There is evidence that controlling *Salmonella* in feed and controlling rodents in poultry houses can have a substantial impact on the level of *Salmonella* in birds entering the slaughter facility.

In the late 1980's, FSIS tested some alternative processing methods at an establishment in Puerto Rico. Two methods included a counterflow scalder and a hot rinse immediately following the scald tank. At the time, FSIS recognized that it may be expensive to retrofit an existing establishment with a counterflow scalder because of the physical space and plumbing required.

Recognizing that other options are available, this analysis develops potential cost estimates based on the addition of TSP rinses. TSP rinse systems for the poultry industry are relatively expensive. It is currently estimated that a TSP installation would cost $40,000 per line with an operating cost of $0.003 per broiler or $0.014 per turkey.

As a low cost option, FSIS assumes that 36 large poultry establishments (27 broiler and 9 turkey establishments) will add TSP systems. Average broiler production is estimated at 35 million and average turkey production at 6 million. Annual average operating cost are, therefore, $105,000 for a chicken slaughter operation and $84,000 for a turkey slaughter operation. Each large poultry establishment is assumed to have 2 lines. Small establishments were assumed to average 1.5 lines.

As a high cost option, FSIS assumes that 182 (100 large and 82 small) poultry establishments will have to add TSP systems to meet the new requirements. The 182 establishments include 136 chicken and 46 turkey slaughter establishments. The total low cost scenario for poultry slaughter operations is summarized in Table 16. The high cost scenario is summarized in Table 17.

TABLE 16.—SALMONELLA TESTING AND PROCESS MODIFICATION COSTS

[Low Cost Scenario—$000]

Industry sector cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
Sampling by Raw Ground Processors	0	363	599	599	599
Process Changes for Cattle and Hog Slaughter Operations	0	86	489	947	947
Sampling by Cattle and Hog Slaughter Operations	0	347	674	674	674
Process changes for poultry slaughter operations	0	4,676	3,591	3,591	3,591
Total	0	5,472	5,353	5,811	5,811

TABLE 17.— SALMONELLA TESTING AND PROCESS MODIFICATION COSTS

[High Cost Scenario—$000]

Industry sector cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
Sampling by raw ground processors	0	$727	$1,904	$1,904	$1,904
Process changes for cattle and hog slaughter operations	0	404	1,063	2,101	2,224
Sampling by cattle and hog slaughter operations	0	2,780	3,807	3,807	3,807
Process Changes for Poultry Slaughter Operations	0	12,988	18,979	18,144	18,144
Total	0	16,899	25,753	25,956	26,079

After the initial implementation years, the annual cost for all three industry sectors is approximately $5.8 million for the low cost scenario. Under the high cost scenario, the total recurring industry cost of meeting the new performance standards is $26.1 million per year.

The high and low cost scenarios have addressed the potential costs of process modification when establishments find they are not meeting critical limits set to assure compliance with the new pathogen reduction standards for *Salmonella.* While the scenarios have addressed permanent process modifications, it is also reasonable to assume that meeting the *Salmonella* standards would involve some day-to-day process adjustments, i.e., corrective actions that do not involve adding new procedures or new equipment. One example would be the decision to reduce line speeds on a day when the incoming live animals are particularly dirty. The Agency believes that many establishments already take this type of precautionary action.

Under HACCP, there will presumably also be some costs associated with corrective actions related to critical limits set for the purpose of meeting existing regulatory limits. As discussed earlier under methodology, the preliminary analysis did not include any costs for taking corrective actions when such deviations from critical limits occur. If this rulemaking were implementing a new regulatory program where none had previously existed, one might expect to see establishments experiencing considerable additional costs due to temporary production down-time, the need to rework or condemn product or the need to

investigate the causes of deviations and develop corrective action plans. Meat and poultry inspection is, however, an existing regulatory program with a broad range of requirements that are well understood by the regulated industry and enforced by the daily presence of an inspector. The system already includes procedures whereby establishments are (1) implementing corrective actions for almost a million written Processing Deficiency Records (PDRs) annually, (2) developing written Establishment Improvement Programs (PIPs) when continuing problems with facility maintenance are observed, and (3) developing Corrective Action Plans when establishments experience serious ongoing problems in complying with existing sanitation or other regulatory requirements. In addition, the regulations already include a wide array of time and/or temperature requirements for cooking and chilling processed products. Many of the existing regulations have been developed with the standards of food safety in mind that are represented by critical limits under HACCP.

Within this existing regulatory framework establishments already experience down-time and expend considerable resources discussing causes of problems and plans for preventing future occurrences. Thus, from the perspective of looking at the existing system, FSIS does not envision that establishments will experience a significant increase in the costs of corrective action and believes the new system can help establishments avoid situations that currently cost them resources to correct. FSIS views the new program as a more effective way of assuring that establishments meet already established health and safety related requirements. For example, the requirement that establishments develop and implement sanitation SOPs does not include any change in existing sanitation standards. Under the existing system, FSIS takes responsibility for determining when establishments meet the standard and when they can operate. Under the new program, establishments will have to document their procedures and take responsibility for implementing those procedures before they begin operations. FSIS recognizes that some establishments will have to spend more time cleaning facilities and equipment. Today, many establishments conduct sanitation procedures only after inspection has identified a problem. FSIS does not, however, view such increased costs of sanitation as a cost of this rulemaking. If this rule imposes such additional costs, it is because the HACCP-based program will inherently provide improved enforcement procedures in situations where firms have been substituting the inspector's sanitation review for their own production control.

In summary, under the broader cost category of process modification and corrective action, FSIS has concluded that the cost of this rule is most appropriately addressed under the subject of potential costs associated with meeting the new pathogen reduction standards. The low and high cost scenarios provide the estimates for these potential costs. As will be discussed under the next topic of generic *E. coli* testing, these low and high cost scenarios include the types of actions establishments would take if they were also experiencing continuing difficulty in meeting criteria established for generic *E. coli.*

The final rule also requires that all establishments that slaughter cattle, swine, chickens or turkeys implement testing programs for generic *E. coli* to validate control of slaughter and sanitary dressing procedures. All samples will be analyzed for quantity, i.e., number of bacteria present. These testing programs will use production volume as the basis for determining the frequency at which establishments will conduct testing for generic *E. coli.* The frequencies for *E. coli* testing for each slaughter species are as follows:

cattle—1 test per 300 carcasses
swine—1 test per 1,000 carcasses
chickens—1 test per 22,000 carcasses
turkeys—1 test per 3,000 carcasses

These frequencies were selected so that, in the subgroup of establishments accounting for 99 percent of total production for each species, the 5 percent of establishments with the highest production volume would each have to conduct a minimum of 13 *E. coli* tests, or one test window, each day. With these frequencies, 90 percent of all cattle, 94 percent of all swine, 99 percent of all chicken, and 99 percent of all turkeys will be slaughtered in establishments conducting a minimum of one *E. coli* test per day.

The above frequencies notwithstanding, all slaughter establishments must conduct sampling at a minimum frequency of once per week. Establishments with very low volumes, slaughtering at or below 6,000 cattle, 20,000 swine (or a combination of such livestock not to exceed a total of 20,000, with a minimum of 6,000 cattle), 440,000 chickens, or 60,000 turkeys annually, will only be required to sample once per week until a sampling window has been completed where the results indicate that the slaughter and dressing process is under control. Once these criteria have been met, these establishments will be required to complete a new sampling window once each year, or when a change has been made in the slaughter process or personnel. This cost analysis assumes that the average low volume establishment will have to complete two windows (26 samples) each year before they meet the established criteria, recognizing that some establishments will meet the criteria on their first window and others may require three or more.

The final rule also provides that slaughter establishments operating under a validated HACCP system may use a sampling frequency other than that provided for in the regulation if the alternative sampling frequency is an integral part of the establishment's HACCP verification procedures and if FSIS does not determine, and notify the establishment in writing, that the alternative frequency is inadequate to verify the effectiveness of the establishmen's slaughter and sanitary dressing controls. In addition, the final rule allows an establishment to use an existing generic *E. coli* sampling program if it can provide the data necessary to show that the existing plan is assuring adequate control. This analysis has not attempted to account for alternative sampling frequencies. It is likely that any reduction in generic *E. coli* sampling would be offset by alternative verification procedures.

The estimated component costs for collecting, shipping and analyzing a generic *E. coli* sample at a commercial laboratory are shown in Table 18.

TABLE 18.—COST OF A GENERIC E. COLI SAMPLE ANALYSIS COMMERCIAL LABORATORY

[Dollars]

Component	Cost
Average private laboratory cost	13.00
Shipping	7.00
Collecting and packaging	3.75
Total	23.75

The component costs for collecting and analyzing a generic *E. coli* sample at an FSIS field laboratory are shown in Table 19.

TABLE 19.— COST OF A GENERIC E. COLI SAMPLE ANALYSIS FSIS FIELD LABORATORY

[Dollars]

Component	Cost
Sample collection supplies	1.45
Sample collection (0.5 hrs/$18.60 per hr)	9.30
Laboratory supplies	2.90
Laboratory analysis (0.5 hrs/$18.60 per hr)	9.30
Total	22.95

Based on the above average cost estimates, this final RIA uses a per sample cost of $24 per analysis, recognizing that establishments with in-house laboratories will be able to conduct sample analysis at lower costs. In using the average cost of $24 per sample, FSIS is providing an upper bound estimate. The corresponding cost per sample for *Salmonella* was $33.35 at a commercial laboratory. Thus, using generic *E. coli* instead of *Salmonella* for process control validation has reduced the per sample cost by approximately 30 percent.

Aggregate annual sampling costs were estimated by applying the sampling frequencies to annual production data recorded by the Animal Disposition Reporting System (ADRS), an existing Agency database. The ADRS includes the total annual production in terms of number of livestock or poultry slaughtered for each federally inspected establishment. Table 20 summarizes estimates for the number of samples that will need to be collected and analyzed each year by the 364 inspected poultry slaughter operations. As shown in Table 20, the 364 establishments will be required to analyze 419,123 samples annually. Table 21 summarizes estimates for the number of samples that will need to be collected and analyzed each year by the 2,318 inspected cattle and swine slaughter operations. As shown in Table 21, the 2,318 establishments will be required to analyze 252,640 samples annually.

The smallest 2,098 slaughter operations (less than 6,000 cattle, 20,000 swine, 60,000 turkeys and 440,000 chickens) will be required to analyze one sample per week until they demonstrate compliance with established criteria. This analysis assumes an average of 26 samples per establishment per year, recognizing that some may need more and others less. These 2,098 smaller slaughter operations (over 78 percent of the total 2,682) will not be required to conduct any further analyses within a given year unless major changes to facilities, equipment or personnel occur.

Tables 20 and 21 were constructed assuming that all establishments operate on a 52 week, 260 day, 40 hours per week, 2,080-hour work-year. As discussed above, this final RIA does not attempt to account for possible reductions in sampling frequency in establishments where the establishment can demonstrate an existing acceptable alternative program or where alternative frequencies are an integral part of successful HACCP verification procedures.

Tables 20 and 21 incorporate data from the preliminary analysis showing that there are 1,328 state-inspected slaughter establishments, with an estimated 1,270 slaughtering cattle or swine and 58 slaughtering poultry. Based on additional data collected in July 1995, FSIS anticipates that 50 of the state-inspected cattle or swine slaughtering establishments will exceed the limits of 6,000 cattle or 20,000 hogs and will be required to conduct a minimum of one sample per week on an ongoing basis. It is further assumed that none of these establishments will have to conduct more than one per week, i.e., cattle slaughter is under 15,600 (300×52) and swine slaughter is under 52,000 (52×1,000). The other 1,220 state-inspected cattle or swine establishments would average 26 samples per year (2 windows). The July 1995 data indicate that all 58 state-inspected establishments slaughtering poultry process fewer than 60,000 turkeys and 440,000 chickens annually.

TABLE 20.—REQUIRED E. COLI SAMPLING FOR POULTRY SLAUGHTER ESTABLISHMENTS

Annual slaughter production category	Number establishments	Sampling range per day	Average sampling rate per establishment	Annual samples
Chickens over 45.8 million	60	Over 8 per day	10.9 Per Day	170,300
Chickens 5.72 to 45.8 million	125	1–8 per day	4.7 per day	152,230
Chickens 440,000 to 5,720,000	23	1 per week-1 per day	1.9 per week	2,215
Turkeys over 6.24 million	18	Over 8 per day	12.7 per day	59,540
Turkeys 780,000 to 6,240,000	25	1–8 per day	4.8 per day	31,330
Turkeys 60,000 to 780,000	5	1 per week-1 per day	2.7 per week	700
Chickens under 440,000 and Turkeys under 60,000	108	NA	One per week (26 weeks)	2,808
Total	364	NA	NA	419,123

NA—Not applicable.

TABLE 21.— REQUIRED GENERIC E. COLI SAMPLING FOR SWINE AND CATTLE SLAUGHTER ESTABLISHMENTS

Annual slaughter production category	Number of establishments	Sampling range	Average sampling rate per establishment	Annual samples
Cattle over 780,000	16	10 or more per day	14.8 per day	61,750
Cattle between 78,000 and 780,000	50	1–10 per day	3.2 Per Day	41,340
Hogs over 2,080,000	17	8 or more per day	11.6 per day	51,090
Hogs between 260,000 and 2,080,000	29	1–8 per day	4.0 Per Day	30,290
Cattle between 6,000 and 78,000 and/or hogs between 20,000 and 260,000.	216	One per week—one per day.	1.5 per week	16,430
Under 6,000 cattle and under 20,000 Hogs	1,990	NA	One per week (26 weeks)	51,740
Total	2,318	NA	NA	252,640

NA—Not applicable.

The total costs for meeting the final requirements for generic *E. coli* sampling in poultry and livestock slaughter establishments are summarized in Tables 22 and 23. These tables use the same cost estimates as the preliminary analysis for requirements such as plan development, training and recording and reviewing analytical results. Plan development is $640 per plan. The preliminary analysis assumed that 75 percent of operations will require training for aseptic sampling at $403 per operation. Recording and reviewing laboratory results averages 5 minutes per sample at an average wage of $13.43.

As shown in Table 22, implementation costs (training and sampling plan development) for generic *E. coli* sampling in poultry establishments will be $286 thousand. For cattle and swine establishments, the implementation costs are $2.34 million as shown in Table 23. Annual recurring costs total $10.5 million for for the 364 poultry establishments and $6.35 million for the 2,318 cattle and swine establishments. The total implementation costs for all 2,682 slaughter establishments are $2.63 million. The total recurring costs are $16.85 million.

In addition to the required sampling costs, there is the question of whether there will be additional compliance costs for establishments where test results indicate the performance criteria generic *E. coli* are not being met. In addressing this question, FSIS considered several factors. First, FSIS acknowledges that some establishments will find they are in compliance with the pathogen reduction standards for *Salmonella*, but are not meeting the performance criteria for generic *E. coli*. Second, the fact that the performance criteria are not established as enforceable regulatory standards does not mean that there will not be compliance costs. Third, the compliance actions identified for meeting the *Salmonella* standards (steam vacuum system, TSP systems and hot water rinses), are the same actions establishments would likely employ to achieve compliance with the performance criteria.

TABLE 22.—COSTS FOR IMPLEMENTING GENERIC E. COLI SAMPLING PROGRAMS IN POULTRY SLAUGHTER ESTABLISHMENTS

[Dollars in Thousands]

Production Category	Number of establishments (number of annual samples)	Training for aseptic sampling	Sampling plan development	Samples collection and analysis (recurring)	Recording and review (recurring)
Turkeys Under 60,000; Chickens Under 440,000	108 (2,808)	44	69	67	3
Turkeys Between 60,000 and 780,000; Chickens Between 440,000 and 5,720,000	28 (2,915)	6	18	70	3
Turkeys over 780,000; Chickens over 5,720,000	228 (413,400)	3	146	9,992	463
Total	364 (419,123)	53	233	10,059	469

TABLE 23.—COSTS FOR IMPLEMENTING GENERIC E. COLI SAMPLING PROGRAMS FOR CATTLE AND SWINE SLAUGHTER ESTABLISHMENTS

[Dollars in Thousands]

Production category	Number of establishments (number of annual samples)	Training for aseptic sampling	Sampling plan development	Samples collection and analysis (recurring)	Recording and review (recurring)
Cattle Under 6,000; Hogs Under 20,000	1,990 (51,740)	802	1,274	1,242	58
Cattle Between 6,000 and 78,000; Hogs Between 20,000 and 260,000	216 (16,430)	54	138	394	18
Cattle over 78,000; Hogs over 260,000	112 (184,470)	1	72	4,427	206
Total	2,318 (252,640)	857	1,484	6,063	283

After considering the above factors, FSIS concluded that if the low cost scenario for compliance with *Salmonella* standards proves to be more accurate, there will likely be more separate compliance costs for generic *E. coli*. As the costs for *Salmonella* compliance go up, the likelihood of separate generic *E. coli* costs goes down. It is important to note that under the high cost scenario, all cattle and swine slaughter establishments are using the steam vacuum system or a hot water rinse and half of all poultry slaughter establishments are using TSP systems. Under this scenario, it is difficult to imagine that any establishments would

still be failing to meet the performance criteria for generic *E. coli.*

FSIS considered the possibility that the smaller establishments conducting only seasonal testing would increase testing to cover the whole year to provide better assurance of control over sanitary dressing procedures. However, FSIS rejected this possibility after considering the cost pressures on small businesses. FSIS would certainly not expect to see these establishments use both expanded testing and hot water rinses.

3. HACCP Programs—Plan Development and Annual Reassessment Costs

a. Summary of Requirements. The proposed rule included a requirement that each inspected establishment develop a written HACCP plan for each distinct ''process'' conducted on the premises. The proposed rule identified nine process categories that would require separate HACCP plans. Each plan would include: identification of the processing steps which present hazards; identification and description of the CCP for each identified hazard; specification of the critical limit which may not be exceeded at the CCP (and if appropriate a target limit); a description of the establishment monitoring procedures; a description of the corrective action to be taken if the limit is exceeded; a description of the records which would be generated and maintained regarding this CCP; and a description of the establishment verification activities and the frequency at which they are to be conducted.

The requirements in the final rule for HACCP plans are essentially the same. The final rule requires that each establishment conduct a hazard analysis and then develop a comprehensive HACCP plan that covers each hazard identified. The final rule has eliminated the nine process categories because the sequencing of HACCP implementation will be based on establishment size and not on process categories. The final rule also includes the provision that each plan be reassessed on an annual basis.

b. Review of Preliminary Cost Estimates. Using existing databases (PBIS and ADRS) FSIS estimated that the 6,186 federally inspected establishments would require 16,899 HACCP plans, an average of 2.73 plans per establishment. It was assumed that each of the 2,893 state inspected establishments would have 2.1 plans per establishment for a total of 6,120 plans. The total number of plans for all establishments is, therefore, 23,019. The Agency requested specific comments on the assumptions used to estimate the number of state plans, but received none. In estimating the cost of HACCP plan development for federally inspected establishments, FSIS used the following cost estimates as shown in Table 24.

TABLE 24.—HACCP PLAN DEVELOPMENT COSTS

Plan difficulty	Plan sequence		
	First	Second	Third
Easy	4,000	2,000	1,000
Moderate	8,000	4,000	2,000
Difficult	12,500	6,250	3,125

Table 24 accounts for both the complexity or difficulty of the plan and the experience gained by developing previous plans. The table was developed from several sources including discussions with a number of private sector food consultants and the results of the *HACCP Pilot Program Cost Findings* study which was conducted by RTI and completed in August 1994. The RTI Study found that the nine pilot establishments reported plan development costs ranging from $607 to $15,750.

For state establishments, FSIS assumed an average cost of $2,000 for 6,120 plans. For the federally-inspected establishments, the above table generated an average cost of approximately $2,020 per plan. The resulting average cost is relatively low because the preliminary analysis credited each establishment with having developed one plan prior to HACCP because of the need to develop plans for sanitation SOPs, microbial sampling and time-temperature controls. It was assumed that the experience gained in developing plans for these three near-term interventions could be applied to their first HACCP plan.

- The total cost for developing 23,019 plans was estimated at approximated $46.4 million ($34.14 million federal and $12.24 million state) spread over a 3 year implementation period.

c. Comments on the Preliminary RIA. There were several specific comments on the cost of developing a HACCP plan. Examples include:

- To write each plan would cost around $9,000.
- Average time to draft a plan is 300 hours.
- Average time of 300 hours at $125 per hour ($37,500).
- An average of $5,000 per establishment.
- Approximately $1,000 to $1,500 per establishment.

More general comments stated that FSIS had underestimated or overestimated the cost of plan development or that FSIS should develop or pay for the cost of developing plans. There were also comments that indicate that some establishments believed that they would be required to have a separate plan for each product they produce.

d. Response to Comments. The comments that suggested FSIS had overestimated costs or had developed an upper limit on implementation costs, pointed out that a market driven response to the rule would likely cut costs. The market would increase the number of consultants which would be available at reduced costs, especially for small establishments that are most likely to employ outside consultants. While FSIS agrees that the number of available consultants will increase and that the hourly cost for outside assistance will likely decrease, the Agency notes that Table 24 was developed with those factors in mind. The discussions with private sector food consultants focused on projected costs, recognizing that costs would decrease as more consultants became available and the overall level of industry expertise and experience increased.

The comments included a wide range of estimates for the cost of developing a HACCP plan. Most of the specific cost estimates contained in the comments were within the ranges presented in Table 24. The comments do not provide a compelling reason to modify Table 24, especially since FSIS has an ongoing effort to develop implementation aids for establishments that will help keep plan development costs down. In addition to generic models that will be available at least six months before any mandatory requirement, FSIS is developing or considering: (1) Information publications, such as a HACCP Handbook that explains how a establishment can effectively and economically incorporate the seven principles into its operations; (2) training videos and computer programs that present HACCP implementation guidance in alternative formats; (3) models for onsite HACCP training of establishment employees; and (4) a catalog of hazards with examples of control measures and generic plans for each slaughter and processing category described in the proposed rule. FSIS is also planning to sponsor in-establishment demonstration projects to generate real-world information and guidance about near-term and HACCP implementation issues in small businesses.

FSIS will also continue its technical assistance to state programs by including states' training officials in

Federal training efforts, by facilitating state access to and use of federal computer support systems, and by expansion of state/federal cooperative efforts through the Conference for Food Protection, the National Association of State Departments of Agriculture, the Association of Food and Drug officials, and the Meat and Poultry Inspection Advisory Committee. Also, FSIS' plans for in-establishment demonstration projects referenced above will focus on small establishments under State regulation as well as those under Federal regulation.

The findings from the nine pilot establishments reported in the RTI study were based on conditions existing in the 1991–1992 time period. Many factors have changed since then including the number of available HACCP consultants, the number of trained individuals, the number of courses available and the general level of knowledge concerning the implementation of HACCP principles in food processing establishments. These factors should help drive plan development cost down.

The 1994 RTI study noted that: ''Several participants commented that there is a lot more discussion and information about HACCP in the trade press and elsewhere today than there was even three years ago. Without exception, participants felt that USDA could reduce the costs of HACCP—especially training and HACCP plan development costs—by making as much information about HACCP available as possible.''

In response to comments that FSIS should develop or pay for the development of plans, FSIS believes that these suggestions would diminish the principle of having industry take ownership and responsibility for the production process. This principle is a key factor in HACCP. If FSIS developed or paid for the plans, it would detract from the establishment's assuming ownership and responsibility for the HACCP plans. FSIS also believes that government funding of the plans would set a bad precedent. If the government assumes the cost of compliance with regulatory actions which ultimately benefit the regulated industry, establishments will campaign for additional actions leading to greater government outlays. Government funded plans would also require an increase in the FSIS budget requiring a corresponding increase in taxes and also likely lead to more expensive plans. By bearing the costs, establishments will have a stronger incentive to control plan development costs than FSIS. Finally, FSIS expects that market forces will permit establishments to shift some of the costs to producers and consumers which is a more equitable allocation of costs than placing the burden on taxpayers in general.

In response to comments expressing concern that each product would require a HACCP plan, FSIS notes that there is a major distinction between requiring that ''each product must be covered by the establishment's HACCP plan'' and requiring that ''each product have a unique HACCP plan.'' The final complexity of an establishment's HACCP plan is related to the number of distinct processes used by the establishment and not the number of products produced.

e. Final Cost Estimates. Although the final rule has eliminated the process categories and requires a single, comprehensive HACCP plan for each establishment with hazards, the final cost estimates are based on the earlier estimates of 16,889 plans for federally inspected establishments and 6,120 plans for state inspected establishments. Since final cost is still a function of the number and complexity of processes, FSIS sees no reason to change the methodology for estimating HACCP plan development costs. Furthermore, it is reasonable to assume that establishments may develop their plans in segments beginning with relatively simple processes and then proceeding to more complex processes.

The final cost estimates for 23,019 HACCP plans are shown in Table 25. The final cost estimate for federally inspected establishments is based on Table 24 which presents different costs, depending on the sequence, for easy, moderate and difficult plans. The final cost estimate does not, however, assume that the first HACCP plan is actually the second plan because of experience gained in developing sanitation SOP plans and microbial sampling plans. The result is that the average cost for the 16,899 plans for federally inspected establishments is now $3,240, up from the preliminary analysis average of $2,020 per plan. The average cost for 6,120 plans in state inspected establishments is $2,000, the same per plan cost used in the preliminary analysis.

It is assumed that HACCP validation is an integral part of HACCP plan development and that the requirement for annual reassessment will be a minimal cost for establishments that do not modify their products or processes and are not experiencing difficulty in meeting all critical limits. The analysis assumes that the average annual reassessment will take two hours per plan at a quality control manager's salary of $25.60 per hour. Thus, the average annual reassessment will cost $51.20 per plan.

TABLE 25.—COST OF HACCP PLAN DEVELOPMENT AND ANNUAL REASSESSMENT

Establishment category	Number establishments	Number plans	Total cost ($000)	Average cost per plan (dollars)	Annual reassessment ($000)
Low	2,234	5,106	17,762	3,479	261
Medium	3,103	8,712	28,075	3,223	446
High	849	3,081	8,911	2,892	158
Subtotal	6,186	16,899	54,748	3,240	865
State	2,893	6,120	12,240	2,000	313
Total	9,079	23,019	66,988	2,910	1,179

As discussed above under methodology, this cost analysis assumes a static number of establishments and processes while recognizing that the rule will add to the cost of new establishments or processes. One such

cost would be the annual reassessment for establishments that add new processes or substantially modify existing production practices.

4. HACCP Programs—Recordkeeping Costs

a. Summary of Requirements. The final rule requires that all establishments record observations when monitoring critical control points and document any deviations and corrective actions taken. The rule also requires a certification review of records by an employee not involved in recording observations. Such recording and certification review of observations at critical control points is a fundamental HACCP principle.

FSIS is requiring that the records involving measurements during slaughter and processing, corrective actions, verification check results, and related activities contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The purpose of this requirement is to assure that both the company and the regulator can readily link a record to a product and the timeframe in which it was processed. FSIS is also requiring that the information be recorded at the time that it is observed and that the record be signed by the operator or observer.

FSIS is also requiring that the HACCP records be certified by a company employee other than the one who produced the record, before the product is distributed in commerce. The purpose of this review is to verify that the HACCP system has been in operation during the production of the product, that it has functioned as designed and that the company is taking full responsibility for the product's meeting applicable regulatory requirements. The employee conducting the certification review must sign the records.

FSIS is also requiring that HACCP plans and records be available for review by program personnel. Records access is necessary to permit verification of all aspects of a HACCP system.

b. Review of Preliminary Cost Estimates. In the preliminary cost analysis, recordkeeping cost was defined to include the time it takes to make observations and record the results of those observations plus the cost of certifying and maintaining records. Several key variables were involved in the estimates for HACCP recordkeeping costs for the preliminary RIA. First, it was established that recordkeeping costs are related to the number of processing lines operating simultaneously and not the number of HACCP plans. That is, an establishment may have several HACCP plans but never have more than one operating at any given time. To estimate recordkeeping costs it was necessary to collect data on the average number of production lines operating per shift. To estimate product lines, data was collected for a sample of low, medium and high volume establishments from each of the FSIS Regional Offices. The data on average number of simultaneous operating lines was collected for processing operations, red meat slaughter operations and poultry slaughter operations for both first and second shifts. Costs were then estimated based on 7,639 federal and 4,080 state inspected operations as shown in Table 26.

TABLE 26.—OPERATIONS IN FEDERAL AND STATE INSPECTED ESTABLISHMENTS

Manufacturing operation	Federal inspected establishments	State inspected establishments	Total
Processing	6,006	2,752	8,758
Meat slaughter	1,327	1,270	2,597
Poultry slaughter	306	58	364
Total	7,639	4,080	11,719

It was further assumed that each State establishment was a single shift establishment and that State establishments would have the same number of production lines as the first shift of a low volume federal establishment.

Other variables included the average number of CCP's per plan and the average amount of time for recording and reviewing records per CCP. For federally inspected establishments, the analysis assumed that processing HACCP plans have an average of 7.4 CCP's and slaughter plans have an average of 5 CCP's. It was assumed that State inspected establishments will average 5 CCP's per HACCP plan. Recording time was estimated at an average of 5 minutes per CCP per shift. Review time for certification was estimated at an average of 2 minutes per CCP per shift. Recording cost was estimated based on an employee earning $12.87 per hour. Certification cost was based on a supervisor or QC technician earning $18.13 per hour. All storage costs were based on a national survey of storage costs showing an average annual cost of $8.40 per square foot.

Total recordkeeping costs are the sum of the costs for three components: Monitoring CCP's and recording findings, certifying records, and storing records. The following calculation for the annual costs of recording the findings from monitoring CCP's in State processing operations illustrates how the above estimates were used in estimating total recordkeeping costs:

Recording Costs For State Processing Operations =
(2,752 operations) × (1.1 average production lines)
× (5 minutes per CCP per day ÷ 60 minutes per hour)
× (5 CCP's per line)
× ($12.87 per hour) × (260 days per year)
= § 4.22 million

The total costs per establishment for recordkeeping, as estimated in the preliminary analysis, are summarized in Table 27. The total aggregate costs are shown in Table 28. The average cost per establishment and the total aggregate costs were reduced to account for the recordkeeping that already occurs in TQC, NELS and SIS establishments.

TABLE 27.—SUMMARY OF RECORDKEEPING COSTS PER ESTABLISHMENT

[Dollars]

Establishment category	Recording observations	Certifying records	Maintaining records	Recurring annual cost
Low	2,560	1,442	28	4,030
Medium	4,202	2,368	52	6,621
High	10,994	6,195	90	17,279
State	2,163	1,219	33	3,415

TABLE 28.—HACCP RECORDKEEPING COSTS

[$ Thousands]

Establishment category	Number of establishments	Annual costs
Low	2,234	9,003
Medium	3,103	20,545
High	849	14,669
Subtotal	6,186	44,217
State	2,893	9,880
Total	9,079	54,097

With the methodology used for estimating recordkeeping costs, it is also possible to look at annual recording and certification cost per operating line. Assuming a line runs 52 weeks, 40 hours per week, 2,080 hours per year,

the average annual recordkeeping cost (excluding any storage costs) for a processing line in a federally inspected establishment would be $3,226.23 ($2,063.40 recording plus $1,162.74 certification). The average annual cost for a federally inspected slaughter line would be $2,179.88 ($1,394.25 recording plus $785.63 certification). All lines in State inspected establishments were assumed to have an annual cost of $2,179.88.

c. Comments on the Preliminary RIA. Most of the comments referring to HACCP recordkeeping costs were general comments that the costs would be extremely burdensome. The comments did not question the methodology used in the preliminary analysis to estimate either recording, reviewing or storage costs. The comments included at least two proposed modifications that would substantially reduce costs. One comment suggested that small establishments record only deviations from the HACCP plan and responses to them. At one of the public hearings a representative from a consumer organization suggested that inspectors could conduct the recordkeeping in small establishments.

d. Response to Comments. FSIS believes that while both of the above suggestions would reduce cost, they both do damage to the concept of HACCP. Having the industry take ownership and responsibility of the production process is a key component of HACCP. Having inspectors conduct the recordkeeping would severely detract from ownership. Furthermore, a fundamental HACCP principle requires that observations be recorded and reviewed at critical points in the manufacturing process on an ongoing basis. Recording only deviations does not meet this principle.

The discussion of sanitation SOP recordkeeping costs identified three factors that affect how one views such costs. At least two of those factors apply here. HACCP recordkeeping is a cost that can be reduced through good management and efficiency and should also decrease with experience. If recordkeeping can be conducted by employees working at a CCP location, the additional cost should be minimal. HACCP should also substantially reduce the time establishment officials currently spend interacting with or responding to inspection findings. In addition to responding to the approximately 700,000 to 800,000 Processing Deficiency Records (PDRs) per year, establishments have thousands of meetings with program officials following reviews conducted by area and regional officials or reviewers from the Program Review Division in Lawrence, Kansas. FSIS believes strongly that establishment officials will find some recordkeeping time from reducing inspection interaction time.

e. Final Cost Estimates. After considering the comments, FSIS does not see a need to adjust the costs estimates shown in Tables 27 and 28. The final aggregate cost estimates for recordkeeping are those shown in Table 28.

5. HACCP Programs-Training Costs

a. Summary of Requirements. The final rule requiring that each establishment have access to a HACCP-trained individual remains identical to the training requirement as proposed. The final rule does not, however, include the proposed requirement that the name and resume of the HACCP-trained individual be on file at the establishment.

b. Review of Preliminary Cost Estimates. The proposed rule included the requirement that each establishment have access to a HACCP-trained individual. In the preliminary cost analysis FSIS pointed out that establishments would have options for meeting that requirement. For example, establishments could train an existing employee or use a consultant on an as-needed basis. To provide a cost estimate, FSIS assumed that each slaughter or processing operation would send one employee to a recognized HACCP course for approximately three days.

The preliminary analysis assumed a combination establishment would require training for both slaughter and processing operations. The preliminary analysis identified 11,719 separate meat slaughter, poultry slaughter and processing operations. The analysis assumed that 5 percent of these operations currently have a trained individual and 11,133 would require training.

Training would be a one-time, up-front expense. The cost of training 11,133 establishment employees at $2,514 each would be approximately $28 million. The $2,514 included tuition for a three-day course, travel expenses and wages. In estimating these costs, FSIS used a listing of 1994 HACCP courses compiled by the USDA Extension Service.

c. Comments on the Preliminary RIA. Most of the comments relating to the cost of training industry personnel were of a general nature (e.g., FSIS underestimated the cost of training) or suggested that all training be funded by USDA. Many small processors lumped training with other requirements and indicated that the cost of implementing HACCP would force them to close. A couple of comments indicated that the commenter believed they would have to hire an additional HACCP-trained employee. Several comments noted that the training costs estimated in the IFSE study were far higher than the costs estimated by FSIS.

d. Response to Comments. With respect to the comments that referred to the higher training costs estimated in the IFSE study, FSIS notes that the IFSE study assumed that training was both an up-front and a continuing annual expense. They also assumed that HACCP training was necessary for top management, supervisors and relevant hourly employees. Since the IFSE study was written with a beef slaughter establishment in mind, it is assumed that the authors believed it is necessary to train some or all of the employees working the dressing line. Under their assumptions, a high turnover would require substantial recurring annual costs.

The FSIS cost estimate was tied to meeting the proposed regulatory requirements. The IFSE estimates are the authors' judgment of what would be required to ''successfully'' implement an effective HACCP program. The IFSE study did not provide any rationale for the cost estimates used. For example, the authors assumed that annual training costs for 5,127 small businesses would be $10,000 each for a total annual cost of $50 million. That estimate would appear high considering the large number of establishments with fewer than five employees.

The IFSE study does raise the issue of whether a single three-day course for one employee is adequate to ensure an effective HACCP program. A low cost ongoing training program may be better. FSIS now plans on having training videos and/or correspondence courses available for each establishment. This will present an easier burden for very small establishments because it will not require having an employee leave on travel to receive training. As the number of available courses and locations increases, travel costs will also decrease. Trade associations can help provide local training for all establishments near large metropolitan areas.

FSIS also recognizes that employee turnover will require some level of recurring cost. The necessity of training new hires should, however, decrease over time as the available pool of HACCP-trained individuals increases. FSIS will, however, include a 10 percent recurring cost in the final cost estimate.

e. Final Cost Estimates. The final training cost estimates are shown in Table 29. The one-time cost of $27,988 thousand is the same cost as estimated for the preliminary analysis. In response to comments, an annual recurring cost of $2.8 million has been added.

TABLE 29.—HACCP—TRAINING COSTS

[$ Thousands]

Establishment category	Number of employees	One-time cost	Recurring costs (10%)
Low	2,610	6,562	656
Medium	3,593	9,033	903
High	1,054	2,650	265
Subtotal	7,257	18,244	1,824
State	3,876	9,744	974
Total	11,133	27,988	2,799

6. HACCP Programs—Impact on Total Quality Control/Overtime Issues

a. Summary of Requirements. The proposed rule did not include proposed revisions to existing Total Quality Control (TQC) regulations. However, the preamble stated that FSIS is considering having HACCP be the only Agency recognized health and safety related process control system. The preliminary RIA published with the proposed rule stated that: ''With the publication of the rule, TQC establishments could lose their authority to produce and ship product after their normal shift production time. As a result, 287 active TQC establishments could begin to incur annual overtime charges.''

The final decisions on TQC regulations have not been made. This final analysis uses the impact on overtime as a conservative estimate of the potential impact of pending decisions.

b. Review of Preliminary Cost Estimates. The Agency's supplemental cost analysis recognized that there are 287 TQC establishments that would incur overtime costs to continue their current operating schedules if the TQC regulations were eliminated. The total cost for these 287 establishments was estimated at $2.1 million per year. The preliminary analysis estimated that the total of 287 included 112 low, 124 medium and 51 high volume producers.

c. Comments on the Preliminary RIA. A TQC establishment commented that under the proposed rule they would have to pay an additional $32,308.80 per year in overtime charges. The establishment commented that these additional overtime charges would equate to a substantial portion of their annual net profit.

d. Response to Comments. The comment from the TQC establishment is consistent with the preliminary analysis that was based on the premise that TQC establishments would lose their authority to produce and ship products after their normal shift production time. If such authority is withdrawn establishments would have to incur overtime charges if they want to continue their present operating schedules.

The establishment estimated its potential overtime cost based on an assumption of 100 percent coverage. If the establishment's overtime hours were covered by a patrol assignment, they would be subject to the provisions of proportional coverage and the actual level of overtime charges could be substantially lower.

Inspection assignments cover 8 hours of regular time and may also include scheduled overtime inspection. An assignment may specify 8 hours in one establishment or direct the inspector to cover multiple establishments, i.e., a patrol assignment where the inspector would spend a portion of each day in each establishment. In cases where an inspector spends 8 hours in a single establishment and that establishment decides to operate for 2 hours of overtime on a routine basis, inspection coverage may be provided by having the assigned inspector work 2 hours of overtime. This type of coverage would be likely if the establishment was located in an isolated area. In this type of case, the establishment would be charged for 2 hours of overtime inspection each day. This type of overtime situation would lead to maximum costs as suggested by the commenter.

If the establishment was part of a patrol assignment and there were two establishments working 2 hours of overtime, the overtime production could be covered by having the inspector work 2 hours of patrol overtime, but each establishment would only be billed for one hour, i.e., proportional overtime coverage.

Because the majority of establishments are covered by patrol assignments, proportional coverage is employed frequently. Thus, the establishments' estimate of $32,308.80 is a maximum level. The actual level of charges could probably be substantially lower.

e. Final Cost Estimates. This final analysis has included a cost of $2.1 million for annual overtime charge. The analysis has assumed that the additional overtime charges will occur on the same timeframe as the sequencing of HACCP implementation.

E. Summary of Costs for Low Volume Producers

Because there has been particular interest in the impact of this rule on small business, this final section summarizes the overall costs for low volume producers. Table 30 illustrates the costs faced by a typical low volume producer over the four-year implementation period. Because there are less than 100 low volume poultry slaughter establishments, the costs for generic *E. coli* sampling was not included in Table 30. The costs illustrated in Table 30 apply to the majority of inspected establishments, an estimated 2,234 federally inspected establishments and all but a few of the 2,893 state inspected establishments. These 5,000-plus establishments all meet the regulatory flexibility definition for a very small establishment and have the full 42 months to implement mandatory HACCP systems. There are another 658 establishments (medium volume production) that will have slightly higher costs, but will also have 42 months to implement HACCP because they meet the regulatory flexibility criteria for a very small establishment. All establishments meeting the regulatory flexibility criteria for small establishments will have 30 months to implement HACCP. The 353 large establishments (more than 500 employees) will be required to implement HACCP 18 months after publication.

TABLE 30.—SUMMARY OF COSTS FOR A TYPICAL LOW VOLUME ESTABLISHMENT

[Dollars]

Cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
I. Sanitation SOPs Plans and Training	[a] 190	.....	.....	.....	
Observation and Recording	1,242	1,242	1,242	1,242	1,242
II. Compliance With *Salmonella* Standards	.....	.....	.....	[b] 0–1,200	[b] 0–1,200

TABLE 30.—SUMMARY OF COSTS FOR A TYPICAL LOW VOLUME ESTABLISHMENT—Continued

[Dollars]

Cost category	Year 1	Year 2	Year 3	Year 4	Year 5+
III. HACCP Plan Development				4,231–7,952	
Annual Plan Reassessment					177
Initial Training				[d] 2,937–3,368	
Recurring Training					294–337
Recordkeeping				2,015	4,030
IV. Additional Overtime				[e] 0–3,702	[e] 0–7,404
Total	1,432	1,242	1,242	10,425–11,625	5,743–6,986

[a] This cost for the 112 low volume TQC establishments would be $64.
[b] The estimate of $1,200 is based on monthly testing for two products and an antimicrobial rinse for one.
[c] The Cost Analysis is based on estimates that low volume federally inspected establishments will require an average of 2.29 plans each, at a cost of $3,479 per plan (see Table 25) for a total average plan development cost of $7,952. The number of plans for federally inspected establishments is based on data from existing FSIS data bases. It was assumed that state plans have an average of 2.12 plans each for a total cost of $4,231 per establishment ($2,000 per plan).
[d] Average training costs for state establishments ($3,368 per establishment) were estimated to be slightly higher than the average federally inspected low volume establishments ($2,937 per establishment) because the state programs have a higher percentage of combination slaughter and processing establishments. The cost analysis assumed that plans would train one individual for each processing, red meat slaughter and poultry slaughter operation.
[e] The preliminary analysis estimated that 112 of 287 active TQC establishments are low volume producers. The average TQC establishment avoids an annual overtime charge of $7,404. The cost estimates in Table 30 for additional overtime costs apply only to those 112 establishments and assume that TQC provisions will be phased out as HACCP is phased in—42 months after publication for the low volume establishments. Because the overtime costs apply to only 112 establishments, they are not included in the Table 30 totals.

The average costs shown in Table 30 will be a burden for many of the low volume producers. However, there are factors that should help diminish the burden. Most of the costs and essentially all of the recurring costs are labor costs for monitoring sanitation procedures, monitoring HACCP critical control points and keeping both HACCP and sanitation records. As the above analysis points out, these are costs that can be reduced through efficient management and allocation of resources and should decrease with experience. The Agency also views a portion of these costs as a shift in resources, i.e., establishment management should spend more resources monitoring establishment operations and less time interacting with program personnel.

Another way of illustrating costs to small businesses is to look at the costs for one or more specific examples. Table 31 illustrates the costs for a small, single-shift, processing establishment (no TQC or sanitation PQC program) with two distinct production operations other than raw ground product (overall average was estimated at 2.29 based on data shown in Table 25).

TABLE 31.—COSTS FOR TYPICAL SINGLE-SHIFT PROCESSING ESTABLISHMENT

[Dollars]

Requirement	Development and Implementation costs	Recurring Annual Costs
Sanitation SOP's ...	190	1,242

TABLE 31.—COSTS FOR TYPICAL SINGLE-SHIFT PROCESSING ESTABLISHMENT—Continued

[Dollars]

Requirement	Development and Implementation costs	Recurring Annual Costs
HACCP Plan Development	6,958	0
Annual Plan Reassessment	0	102
Training	2,514	251
Recordkeeping	0	6,480
Total	9,662	8,075

If one of the two production operations produced a raw ground product, the establishment would have to meet the pathogen reduction performance standard for that product. As noted earlier in the development of the low and high cost scenarios for meeting the new *Salmonella* standards, raw ground operations do not have the same opportunities to reduce *Salmonella* levels as do slaughter establishments. They can control growth by avoiding temperature abuse and can limit cross-contamination, but basically they must depend on the Salmonella levels of their incoming product in order to meet the performance standards. These establishments may choose to test incoming product in order to eliminate suppliers whose product is found to be positive. The final analysis has assumed that the low volume producers would not test incoming ingredients.

Table 32 illustrates the costs for a small, single-shift, combination (slaughter and further processing) establishment that slaughters cattle or swine, but not both, and has a single further processing operation other than raw ground product. The establishment is not under TQC inspection.

TABLE 32.—COSTS FOR TYPICAL SINGLE-SHIFT COMBINATION ESTABLISHMENT

[Dollars]

Requirement	Development and implementation costs	Recurring annual costs
Sanitation SOP's ...	190	1,242
Compliance with *Salmonella* Standards	0	800
E. coli Sampling	1,043	653
HACCP Plan Development	6,958	0
Annual Plan Reassessment	0	102
Training	5,028	503
Recordkeeping	0	5,434
Total	13,219	8,734

The cost of meeting the pathogen reduction performance standards assumes that the establishment will use a hot water antimicrobial rinse and have one sample per month analyzed at an outside laboratory ($33.35 per sample-$400 per year). The average number of head slaughtered in a low volume establishment is approximately 5,000

annually. The annual cost for the rinse is $400.

The development costs for *E. coli* sampling in the small establishment includes $640 for developing a sampling plan and $403 to train an individual to conduct aseptic sampling. The recurring costs are based on the assumption that an average low volume slaughter establishment will have to complete two sampling windows (26 samples) before they demonstrate compliance with established criteria.

The cost of HACCP training has doubled for the combination establishment because the FRIA assumed that slaughter and processing operations are significantly different, so that the establishment must either train two employees or send one employee to two separate training courses.

The HACCP recordkeeping costs (monitoring CCP's and recording findings, reviewing records and storing records) in the above two examples assume that the establishments are operating each process continuously over a standard 52-week, 260-day, 2,080-hour work year. Data collected during the preliminary analysis indicates that many low volume establishments frequently have only a single production line operating at a given time. As shown in Tables 27 and 30, the final analysis estimates an average annual cost for HACCP recordkeeping of $4,030 for low volume establishments.

Appendix A to Final Regulatory Impact Assessment

Response to Comments Related to the Preliminary Regulatory Impact Analysis But Not Addressed Directly in the Text of the Final Analysis

1. A comment noting that the ''data in Tables 1 and 2, (60 FR 6781) for *Toxoplasma gondii* are confusing or in error'' is correct. The tables as published contained typographical errors that have been corrected for this analysis. The number of cases of foodborne illness from toxoplasmosis should be 2,056 cases, not 3,056 cases. The total number of cases from the foodborne illnesses considered also needs to be adjusted to correct for the above typographical error. Specifically, the total number of cases should be 3,605,582 to 7,132,823, and not 3,606,582 to 7,133,823.

2. The same comment questioned whether it is true that the ''estimated medical costs for the 2,056 cases (toxoplasmosis) and 41 deaths is $2,7000,000,000?'' This estimate is correct but these costs include the estimated costs of lost productivity and costs of residential care as well as the estimated medical costs of toxoplasmosis.

3. There were several comments that indicated that while attempting to reduce the overall public health risk, the Agency could be increasing the risk to farmers and small producers that now have livestock custom-slaughtered at inspected establishments. If a large number of these small diverse businesses go under, the comments predicted an increase in at- home slaughter under very marginal conditions. These comments imply at-home slaughter is a high risk practice using terms such as barn yard butchering or shade tree butchering or back shed butchering.

Changes in the final rule should allow most small businesses to continue to operate successfully under inspection. There are some small businesses that are currently primarily custom-exempt/ retail exempt operations that may choose to withdraw from inspection. These types of facilities will still be available for their custom slaughtering services.

4. A comment referred to the FSIS assertion that consideration of the costs of the various alternatives under examination is not relevant because the alternatives do not meet the Agency's goal of achieving the maximum pathogen reduction possible. The commenter concluded that this is an entirely inappropriate analytical framework for the examination of regulatory alternatives. By starting from the assumption that only the maximum benefit attainable will suffice, FSIS effectively renders its consideration of available regulatory alternatives a complete sham. The purpose of a regulatory impact assessment should be to examine both the benefits and the costs attributable to each available alternative, and to consider whether there is an alternative to the Agency proposal that is a more cost-effective means of addressing the problem at hand.

5. One commenter stated that the Agency must include the costs attributable to the retained requirements as well. These retained costs will significantly increase the operational costs of the combined, layered system. FSIS does not agree that the RIA needs to include the cost of existing requirements.

6. Comments expressed concern that the proposed rule was an experiment to collect the data needed to determine whether it was a good idea. These comments stated that industry should not bear the cost of a government research project. FSIS has clearly stated the public health objective of this rule.

7. There are several comments that referred to a study conducted by the Research Triangle Institute for FSIS. In that study, *HACCP Pilot Programs Cost Findings,* August 31, 1994, RTI collected cost information during personal interviews at all nine establishments that had participated in USDA's HACCP Model Pilot Program.

One comment noted that the pilot establishments used for the study are establishments that are larger than most of the establishments that are going to be affected. The RTI study noted that none of the voluntary participants have annual sales under $3 million. The RTI study was one source of information for the FSIS cost analysis. The Agency did not use the information in a way that suggested it was representative of all establishments or in any way imply that it was.

Another comment stated that USDA relied very heavily on the nine pilot establishment studies. The data collected by RTI was one source of information used for the preliminary cost analysis. The analysis clearly cites the RTI study as one of several data sources.

A comment during the public hearing attributed a cost of $23,000 or $27,000 to the RTI study for a hazard analysis, plan development and validation for a small business that doesn't need any equipment or establishment upgrade. The RTI study reported costs for plan development ranging from $607 to $15,750. FSIS assumes that the hazard analysis is part of plan development. The RTI study did not address a separate cost component for validation.

8. One comment indicated that the source of the estimates for total cases and deaths for *E. coli* O157:H7 does not support the number used in the benefit estimates. The preliminary analysis was based on 10,000–20,000 total cases and an estimate of from 200–500 total deaths. Sources identified were the AGA conference and CDC communications. The ''CDC comm.'' citation mentioned in the FSIS proposal refers to both the Ostroff et al. (1989) and the McDonald et al. (1988) articles as described in the comment. These references provide an incidence rate for *E. coli* O157:H7 of 2.1/100,000 to 8/ 100,000. The AGA conference suggests there are 10,000 to 20,000 cases of *E. coli* O157:H7 each year in the United States. This translates to a rate of approximately 4/100,000 to 8/100,000, which is higher on the lower estimate. ERS chose to use the consensus numbers because they reflect the current thinking of a nonadvocate panel of experts. FSIS agrees with the commenter that better data on

foodborne disease incidence is needed but believe that the preliminary analysis used the best estimates available.

9. Commenter stated FSIS relied on faulty data. FSIS responds that there is a difference between saying data are limited and saying data are faulty. Existing food safety data are limited and more thorough data may not be available for a long time.

10. A commenter noted that FSIS did not address the ''cost'' of the development of a highly susceptible population because some exposure is necessary to establish immunity. The same commenter suggested there might be a ''nutritional health'' cost penalty, i.e., the rule would increase the cost of food so much that consumers would not be able to afford nutritional food. FSIS notes that the commenter did not provide support for these ''costs.''

11. A commenter noted that their low annual insurance premium of $150 strongly suggests that the insurance industry considers their existing safety record commendable and worthy of a low liability rate. FSIS notes that another comment has suggested that lower rates are being offered in conjunction with improved process control systems.

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